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Address to:

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Attorney's Docket No. ENVS-220

First Named Inventor Csaba Truckai

UTILITY PATENT APPLICATION TRANSMITTAL
(under 37 CFR 1.53(b))

THIS APPLICATION CLAIMS THE BENEFIT OF U.S. PROVISIONAL APPLICATION NO. 60/084,791, FILED MAY 8, 1998, AND IS A CONTINUATION-IN-PART OF COPENING U.S. APPLICATION NO. 08/632,516, FILED APRIL 12, 1996, NOW U.S. PATENT NO. 5,769,880, ISSUED JUNE 23, 1998.

Transmitted herewith for filing is a **CONTINUATION-IN-PART** patent application entitled:

A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

CERTIFICATION UNDER 37 CFR § 1.10

I hereby certify that this New Application and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date June 23, 1998, in an envelope bearing "Express Mail Post Office To Addressee" Mailing Label Number **EM503277278US** addressed to: Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

ELIZABETH A. REICKER

(Name of person mailing paper)

Elizabeth A. Reicker
(Signature)

Enclosed are:

1. ☒ Transmittal Form (two copies required)
2. The papers required for filing date under CFR § 1.53(b):
 - i. 49 Pages of specification (including claims and abstract);
 - ii. 19 Sheets of drawings.
 ☐ formal ☒ informal
3. Declaration or oath
 - a. ☒ Unsigned Declaration (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Item 12 completed)
☐ Incorporation By Reference (to be used if Item 3b is checked)

The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Item 3b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

- i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)
4. ☐ Microfiche Computer Program (Appendix, see 37 CFR 1.96)
5. ☐ Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - i. ☐ Computer Readable Copy
 - ii. ☐ Paper Copy (identical to computer copy)
 - iii. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

6. ☐ An assignment of the invention to is attached (including Form PTO-1595).

- ☐ The prior application is assigned of record to ;
Assignment recorded in PTO on __, Reel __, Frame(s) __.
- ☐ The prior application is assigned, and the assignment (copy attached) was submitted to PTO for recording on __.
- i. ☐ 37 CFR 3.73(b) Statement (when there is an assignee)
7. ☐ Power of Attorney
8. ☐ An Information Disclosure Statement (IDS) is enclosed, including a PTO-1449 and copies of __ references.
9. ☐ Preliminary Amendment.
10. ☒ Return Receipt Postcard (MPEP 503 -- should be specifically itemized)
11. ☐ Other
12. If a **CONTINUING APPLICATION**, *check appropriate box and supply the requisite information*

- ☐ Continuation
☐ Divisional
☒ Continuation-In-Part (CIP)

of immediately prior application no. 08/632,516, filed April 12, 1996, now Patent No. 5,769,880,
Issued June 23, 1998 and claims benefit of U.S. Provisional Application No. 60/084,791, filed May 8, 1998.

- i. **RELATE BACK - 35 USC 120:** If one of the above boxes are checked, please amend the specification by inserting before the first line the sentence: --This is a continuation-in-part of Application no. 08/632,516, filed April 12, 1996, now Patent No. 5,769,880, issued June 23, 1998 and claims benefit of U.S. Provisional Application No. 60/084,791, filed May 8, 1998.--
- ii. **MAINTENANCE OF COPENDENCY OF PRIOR APPLICATION**
(This item must be completed and the necessary papers filed in the prior application if the period set in the prior application has run).
☐ A petition, fee and response has been filed to extend the term in the pending prior application until __.
☐ A copy of the petition for extension of time in the prior application is attached.
- iii. **CONDITIONAL PETITIONS FOR EXTENSION OF TIME IN PRIOR APPLICATION**
(Complete this item and file conditional petition in prior application if previous item (ii) not applicable).
☐ A conditional petition for extension of time is being filed in the pending prior application.
☐ A copy of the conditional petition for extension of time in the prior application is attached.

13. **FOREIGN PRIORITY**

- ☐ Priority of application no. __ filed on __ in __ is claimed under 35 USC 119.

The certified copy of the priority application:

- ☐ is filed herewith; or
☐ has been filed in prior application no. __ filed on __, or
☐ will be provided.

☐ English Translation Document (if applicable)

14. FEE CALCULATION

- a. ☐ Amendment changing number of claims or deleting multiple dependencies is enclosed.
- b. ☐ Cancel in this application original Claims ☐ of the prior application before calculating the filing fee.

CLAIMS AS FILED

	Number Filed	Number Extra	Rate	Basic Fee (\$790)
Total Claims	31 - 20	* 11	x \$22.00	\$242.00
Independent Claims	3 - 3	* -0-	x \$82.00	-0-
Multiple dependent claim(s), if any			\$270.00	-0-

*If less than zero, enter "0".

Filing Fee Calculation \$1032.00

50% Filing Fee Reduction (if applicable) \$516.00

15. Small Entity Status

- a. ☒ A small entity statement is enclosed. (unsigned)
- b. ☐ A small entity statement was filed in the prior nonprovisional application and such status is still proper and desired.
- c. ☐ is no longer claimed.

16. Other Fees

- ☐ Recording Assignment [\$40.00] \$
- ☐ Other fees
- ☐ Specify _____ \$

Total Fees Enclosed \$

17. Payment of Fees

- ☐ Check(s) in the amount of \$__ enclosed.
- ☐ Charge Account No. 12-1420 in the amount of \$__.
- A duplicate of this transmittal is attached.**

18. All correspondence regarding this application should be forwarded to the undersigned attorney:

Kathleen A. Frost
Limbach & Limbach L.L.P.
2001 Ferry Building
San Francisco, CA 94111
Telephone: 415/433-4150
Facsimile: 415/433-8716

19. Authorization to Charge Additional Fees

- ☒ The Commissioner is hereby authorized to charge any additional fees (or credit any overpayment) associated with this communication and which may be required under 37 CFR § 1.16 or § 1.17 to Account No. 12-1420. **A duplicate of this transmittal is attached.**

LIMBACH & LIMBACH L.L.P.

June 23, 1998
(Date)

Attorney Docket No. ENVS-220
[]

By: Kathleen A. Frost
Kathleen A. Frost
Registration No. 37,326
Attorney(s) or Agent(s) of Record

**A MOISTURE TRANSPORT SYSTEM FOR CONTACT
ELECTROCOAGULATION**

Related Applications

5 This application claims the benefit of U.S. Provisional
Application No. 60/084,791, filed May 8, 1998, and is a
Continuation in Part of copending U.S. Application No. 08/632,516,
filed April 12, 1996, now U.S. Patent No. 5,769,880, issued June
23, 1998.

Field of the Invention

10 The present invention relates generally to the field of
apparatuses and methods for ablating or coagulating the interior
surfaces of body organs. Specifically, it relates to an apparatus and
method for ablating the interior linings of body organs such as the
uterus and gallbladder.

15 Background of the Invention

Ablation of the interior lining of a body organ is a procedure
which involves heating the organ lining to temperatures which
destroy the cells of the lining or coagulate tissue proteins for
hemostasis. Such a procedure may be performed as a treatment to
20 one of many conditions, such as chronic bleeding of the endometrial
layer of the uterus or abnormalities of the mucosal layer of the
gallbladder. Existing methods for effecting ablation include
circulation of heated fluid inside the organ (either directly or inside a

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balloon), laser treatment of the organ lining, and resistive heating using application of RF energy to the tissue to be ablated.

U.S. Patent 5,084,044 describes an apparatus for endometrial ablation in which a bladder is inserted into the uterus. Heated fluid
5 is then circulated through the balloon to expand the balloon into contact with the endometrium and to ablate the endometrium thermally. U.S. Patent 5,443,470 describes an apparatus for endometrial ablation in which an expandable bladder is provided with electrodes on its outer surface. After the apparatus is positioned
10 inside the uterus, a non-conductive gas or liquid is used to fill the balloon, causing the balloon to push the electrodes into contact with the endometrial surface. RF energy is supplied to the electrodes to ablate the endometrial tissue using resistive heating.

These ablation devices are satisfactory for carrying out
15 ablation procedures. However, because no data or feedback is available to guide the physician as to how deep the tissue ablation has progressed, controlling the ablation depth and ablation profile with such devices can only
be done by assumption.

20 For example, the heated fluid method is a very passive and ineffective heating process which relies on the heat conductivity of the tissue. This process does not account for variations in factors such as the amount of contact between the balloon and the underlying tissue, or cooling effects such as those of blood
25 circulating through the organ. RF ablation techniques can achieve more effective ablation since it relies on active heating of the tissue using RF energy, but presently the depth of ablation using RF

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techniques can only be estimated by the physician since no feedback can be provided as to actual ablation depth.

Both the heated fluid techniques and the latest RF techniques must be performed using great care to prevent over ablation.

5 Monitoring of tissue surface temperature is normally carried out during these ablation procedures to ensure the temperature does not exceed 100° C. If the temperature exceeds 100° C, the fluid within the tissue begins to boil and to thereby produce steam. Because
10 ablation is carried out within a closed cavity within the body, the steam cannot escape and may instead force itself deeply into the tissue, or it may pass into areas adjacent to the area intended to be ablated, causing embolism or unintended burning.

Moreover, in prior art RF devices the water drawn from the tissue creates a path of conductivity through which current traveling
15 through the electrodes will flow. This can prevent the current from traveling into the tissue to be ablated. Moreover, the presence of this current path around the electrodes causes current to be continuously drawn from the electrodes. The current heats the liquid drawn from the tissue and thus turns the ablation process into
20 a passive heating method in which the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths.

Another problem with prior art ablation devices is that it is difficult for a physician to find out when ablation has been carried
25 out to a desired depth within the tissue. Thus, it is often the case that too much or too little tissue may be ablated during an ablation procedure.

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It is therefore desirable to provide an ablation device which eliminates the above-described problem of steam and liquid buildup at the ablation site. It is further desirable to provide an ablation method and device which allows the depth of ablation to be controlled and which automatically discontinues ablation once the desired ablation depth has been reached.

Summary Of The Invention

The present invention is an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ. An ablation device is provided which has an electrode array carried by an elongate tubular member. The electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon. During use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue.

Brief Description Of The Drawings

Fig. 1 is a front elevation view of a first embodiment of an ablation device according to the present invention, with the handle shown in cross-section and with the RF applicator head in a closed condition.

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Fig. 2 is a front elevation view of the ablation device of Fig. 1, with the handle shown in cross-section and with the RF applicator head in an open condition.

Fig. 3 is a side elevation view of the ablation device of Fig. 2.

5 Fig. 4 is a top plan view of the ablation device of Fig. 2.

Fig. 5A is a front elevation view of the applicator head and a portion of the main body of the ablation device of Fig. 2, with the main body shown in cross-section.

10 Fig. 5B is a cross-section view of the main body taken along the plane designated 5B-5B in Fig. 5A.

Fig. 6 is a schematic representation of a uterus showing the ablation device of Fig. 1 following insertion of the device into the uterus but prior to retraction of the introducer sheath and activation of the spring members.

15 Fig. 7 is a schematic representation of a uterus showing the ablation device of Fig. 1 following insertion of the device into the uterus and following the retraction of the introducer sheath and the expansion of the RF applicator head.

20 Fig. 8 is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of Fig. 1, showing the RF applicator head in the closed condition.

25 Fig. 9 is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of Fig. 1, showing the configuration of RF applicator head after the sheath has been retracted but before the spring members have been released by proximal movement of the shaft.

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Fig. 10 is a cross-section view of the RF applicator head and the distal portion of the main body of the apparatus of Fig. 1, showing the configuration of RF applicator head after the sheath has been retracted and after the spring members have been released into the fully opened condition.

Fig. 11 is a cross-section view of a distal portion of an RF ablation device similar to Fig. 1 which utilizes an alternative spring member configuration for the RF applicator head.

Fig. 12 is a side elevation view of the distal end of an alternate embodiment of an RF ablation device similar to that of Fig. 1, which utilizes an RF applicator head having a modified shape.

Fig. 13 is a top plan view of the ablation device of Fig. 12.

Fig. 14 is a representation of a bleeding vessel illustrating use of the ablation device of Fig. 12 for general bleeding control.

Figs. 15 and 16 are representations of a uterus illustrating use of the ablation device of Fig. 12 for endometrial ablation.

Fig. 17 is a representation of a prostate gland illustrating use of the ablation device of Fig. 12 for prostate ablation.

Fig. 18 is a cross-section view of target tissue for ablation, showing ablation electrodes in contact with the tissue surface and illustrating energy fields generated during bi-polar ablation.

Figs. 19A - 19C are cross-section views of target tissue for ablation, showing electrodes in contact with the tissue surface and illustrating how varying active electrode density may be used to vary the ablation depth.

Fig. 20 is a side elevation view, similar to the view of Fig. 2, showing an ablation device according to the present invention in

which the electrode carrying means includes inflatable balloons. For purposes of clarity, the electrodes on the electrode carrying means are not shown.

Fig. 21 is a side elevation view of a second exemplary embodiment of an ablation device according to the present invention, showing the array in the retracted state.

Fig. 22 is a side elevation view of the ablation device of Fig. 21, showing the array in the deployed state.

Fig. 23 is a top plan view of the applicator head of the apparatus of Fig. 21.

Fig. 24 is a cross-sectional top view of the encircled region designated 24 in Fig. 23.

Fig. 25A is a perspective view of the electrode array of Fig. 23.

Fig. 25B is a distal end view of the applicator head of Fig. 30A.

Fig. 26A is a plan view of a knit that may be used to form the applicator head.

Fig. 26B is a perspective view of a strand of nylon-wrapped spandex of the type that may be used to form the knit of Fig. 26A.

Figs. 27A, 27B, 27C are top plan views illustrating triangular, parabolic, and rectangular mesh shapes for use as electrode arrays according to the present invention.

Fig. 28 is a perspective view showing the flexures and hypotube of the deflecting mechanism of the applicator head of Fig. 23.

Fig. 29 is a cross-section view of a flexure taken along the plane designated 29-29 in Fig. 23.

Fig. 30 is a top plan view illustrating the flexure and spring arrangement of an alternative configuration of a deflecting mechanism for an applicator head according to the present invention.

Fig. 31 is a cross-sectional side view of the bobbin portion of the apparatus of Fig. 21.

Fig. 32A is a side elevation view of the handle of the ablation device of Fig. 21.

Fig. 32B is a top plan view of the handle of the ablation device of Fig. 21. For clarity, portions of the proximal and distal grips are not shown.

Fig. 33 illustrates placement of the applicator head according to the present invention in a uterine cavity.

Fig. 34 is a side elevation view of the handle of the ablation apparatus of Fig. 21, showing portions of the apparatus in cross-section.

Fig. 35 is a front elevation view of the upper portion of the proximal handle grip taken along the plane designated 35-35 in Fig. 32B.

Figs. 36A, 36B, and 36C are a series of side elevation views illustrating the heel member as it becomes engaged with the corresponding spring member.

Figs. 37A and 37B are cross-sectional top views of the frame member mounted on the proximal grip section, taken along the plane designated 37-37 in Fig. 34 and illustrating one of the load limiting

features of the second embodiment. Fig. 37A shows the condition of the compression spring before the heel member moves into abutment with frame member, and Fig 37B shows the condition of the spring after the heel member moves into abutment with the frame member.

Detailed Description

The invention described in this application is an aspect of a larger set of inventions described in the following co-pending applications which are commonly owned by the assignee of the present invention, and are hereby incorporated by reference: U.S. Provisional Patent Application No. 60/084,724, filed May 8, 1998, entitled "APPARATUS AND METHOD FOR INTRA-ORGAN MEASUREMENT AND ABLATION" (attorney docket no. ENV5-400); and U.S. Provisional Patent Application No. _____ filed May 8, 1998, entitled "A RADIO-FREQUENCY GENERATOR FOR POWERING AN ABLATION DEVICE" (attorney docket no. ENV5-500).

The ablation apparatus according to the present invention will be described with respect to two exemplary embodiments.

First Exemplary Embodiment - Structure

Referring to Figs. 1 and 2, an ablation device according to the present invention is comprised generally of three major components: RF applicator head 2, main body 4, and handle 6. Main body 4 includes a shaft 10. The RF applicator head 2 includes an electrode carrying means 12 mounted to the distal end of the shaft 10 and an array of electrodes 14 formed on the surface of the electrode

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carrying means 12. An RF generator 16 is electrically connected to the electrodes 14 to provide mono-polar or bipolar RF energy to them.

Shaft 10 is an elongate member having a hollow interior. Shaft 10 is preferably 12 inches long and has a preferred cross-sectional diameter of approximately 4 mm. A collar 13 is formed on the exterior of the shaft 10 at the proximal end. As best shown in Figs. 6 and 7, passive spring member 15 are attached to the distal end of the shaft 10.

Extending through the shaft 10 is a suction/insufflation tube 17 (Figs. 6-9) having a plurality of holes 17a formed in its distal end. An arched active spring member 19 is connected between the distal ends of the passive spring members 15 and the distal end of the suction/insufflation tube 17.

Referring to Fig. 2, electrode leads 18a and 18b extend through the shaft 10 from distal end 20 to proximal end 22 of the shaft 10. At the distal end 20 of the shaft 10, each of the leads 18a, 18b is coupled to a respective one of the electrodes 14. At the proximal end 22 of the shaft 10, the leads 18a, 18b are electrically connected to RF generator 16 via an electrical connector 21. During use, the leads 18a, 18b carry RF energy from the RF generator 16 to the electrodes. Each of the leads 18a, 18b is insulated and carries energy of an opposite polarity than the other lead.

Electrically insulated sensor leads 23a, 23b (Figs. 5A and 5B) also extend through the shaft 10. Contact sensors 25a, 25b are attached to the distal ends of the sensor leads 23a, 23b, respectively and are mounted to the electrode carrying means 12.

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During use, the sensor leads 23a, 23b are coupled by the connector 21 to a monitoring module in the RF generator 16 which measures impedance between the sensors 25a, 25b. Alternatively, a reference pad may be positioned in contact with the patient and the impedance between one of the sensors and the reference pad measured.

Referring to Fig. 5B, electrode leads 18a, 18b and sensor leads 23a, 23b extend through the shaft 10 between the external walls of the tube 17 and the interior walls of the shaft 10 and they are coupled to electrical connector 21 which is preferably mounted to the collar 13 on the shaft 10. Connector 21, which is connectable to the RF generator 16, includes at least four electrical contact rings 21a - 21d (Figs. 1 and 2) which correspond to each of the leads 18a, 18b, 23a, 23b. Rings 21a, 21b receive, from the RF generator, RF energy of positive and negative polarity, respectively. Rings 21c, 21d deliver signals from the right and left sensors, respectively, to a monitoring module within the RF generator 16.

Referring to Fig. 5A, the electrode carrying means 12 is attached to the distal end 20 of the shaft 10. A plurality of holes 24 may be formed in the portion of the distal end 20 of the shaft which lies within the electrode carrying means 12.

The electrode carrying means 12 preferably has a shape which approximates the shape of the body organ which is to be ablated. For example, the apparatus shown in Figs. 1 through 11 has a bicornual shape which is desirable for intrauterine ablation. The electrode carrying means 12 shown in these figures includes horn regions 26 which during use are positioned within the cornual

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regions of the uterus and which therefore extend towards the fallopian tubes.

Electrode carrying means 12 is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression. Examples of preferred materials for the electrode carrying means include open cell sponge, foam, cotton, fabric, or cotton-like material, or any other material having the desired characteristics. Alternatively, the electrode carrying means may be formed of a metallized fabric. For convenience, the term "pad" may be used interchangeably with the term electrode carrying means to refer to an electrode carrying means formed of any of the above materials or having the listed properties.

Electrodes 14 are preferably attached to the outer surface of the electrode carrying means 12, such as by deposition or other attachment mechanism. The electrodes are preferably made of lengths of silver, gold, platinum, or any other conductive material. The electrodes may be attached to the electrode carrying means 12 by electron beam deposition, or they may be formed into coiled wires and bonded to the electrode carrying member using a flexible adhesive. Naturally, other means of attaching the electrodes, such as sewing them onto the surface of the carrying member, may alternatively be used. If the electrode carrying means 12 is formed of a metallized fabric, an insulating layer may be etched onto the fabric surface, leaving only the electrode regions exposed.

The spacing between the electrodes (i.e. the distance between the centers of adjacent electrodes) and the widths of the electrodes are selected so that ablation will reach predetermined depths within the tissue, particularly when maximum power is delivered through the electrodes (where maximum power is the level at which low impedance, low voltage ablation can be achieved).

The depth of ablation is also effected by the electrode density (i.e., the percentage of the target tissue area which is in contact with active electrode surfaces) and may be regulated by pre-selecting the amount of this active electrode coverage. For example, the depth of ablation is much greater when the active electrode surface covers more than 10% of the target tissue than it is when the active electrode surfaces covers 1% of the target tissue.

For example, by using 3-6 mm spacing and an electrode width of approximately 0.5 - 2.5 mm, delivery of approximately 20 - 40 watts over a 9-16 cm² target tissue area will cause ablation to a depth of approximately 5-7 millimeters when the active electrode surface covers more than 10% of the target tissue area. After reaching this ablation depth, the impedance of the tissue will become so great that ablation will self-terminate as described with respect to the operation of the invention.

By contrast, using the same power, spacing, electrode width, and RF frequency will produce an ablation depth of only 2 - 3 mm when the active electrode surfaces covers less than 1 % of the target tissue area. This can be better understood with reference to Fig. 19A, in which high surface density electrodes are designated 14a and low surface density electrodes are designated 14b. For

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purposes of this comparison between low and high surface density electrodes, each bracketed group of low density electrodes is considered to be a single electrode. Thus, the electrode widths W and spacings S extend as shown in Fig. 19A.

As is apparent from Fig. 19A, the electrodes 14a, which have more active area in contact with the underlying tissue T, produce a region of ablation A1 that extends more deeply into the tissue T than the ablation region A2 produced by the low density electrodes 14b, even though the electrode spacings and widths are the same for the high and low density electrodes.

Some examples of electrode widths, having spacings with more than 10% active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm² and a power of 20 - 40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1 - 2 mm	1 - 3 mm
1 - 2.5 mm	3 - 6 mm	5 - 7 mm
1 - 4.5 mm	8 - 10 mm	8 - 10 mm

Examples of electrode widths, having spacings with less than 1 % active electrode surface coverage, and their resultant ablation depth, based on an ablation area of 6 cm² and a power of 20 - 40 watts, are given on the following table:

ELECTRODE WIDTH	SPACING	APPROX. DEPTH
1 mm	1 - 2 mm	0.5 - 1 mm
1 - 2.5 mm	3 - 6 mm	2 - 3 mm
1 - 4.5 mm	8 - 10 mm	2 - 3 mm

5 Thus it can be seen that the depth of ablation is significantly less when the active electrode surface coverage is decreased.

10 In the preferred embodiment, the preferred electrode spacing is approximately 8 - 10 mm in the horn regions 26 with the active electrode surfaces covering approximately 1% of the target region. Approximately 1 - 2 mm electrode spacing (with 10% active electrode coverage) is preferred in the cervical region (designated 28) and approximately 3 - 6 mm (with greater than 10% active electrode surface coverage) is preferred in the main body region.

15 The RF generator 16 may be configured to include a controller which gives the user a choice of which electrodes should be energized during a particular application in order to give the user control of ablation depth. For example, during an application for which deep ablation is desired, the user may elect to have the generator energize every other electrode, to thereby optimize the effective spacing of the electrodes and to decrease the percentage of active electrode surface coverage, as will be described below with respect to Fig. 18.

20 Although the electrodes shown in the drawings are arranged in a particular pattern, it should be appreciated that the electrodes

may be arranged in any pattern to provide ablation to desired depths.

Referring to Figs. 6 and 7, an introducer sheath 32 facilitates insertion of the apparatus into, and removal of the apparatus from, the body organ to be ablated. The sheath 32 is a tubular member which is telescopically slidable over the shaft 10. The sheath 32 is slidable between a distal condition, shown in Fig. 6, in which the electrode carrying means 12 is compressed inside the sheath, and a proximal condition in which the sheath 32 is moved proximally to release the electrode carrying means from inside it (Fig. 7). By compressing the electrode carrying means 12 to a small volume, the electrode carrying means and electrodes can be easily inserted into the body cavity (such as into the uterus via the vaginal opening).

A handle 34 attached to the sheath 32 provides finger holds to allow for manipulation of the sheath 32. Handle 34 is slidably mounted on a handle rail 35 which includes a sleeve 33, a finger cutout 37, and a pair of spaced rails 35a, 35b extending between the sleeve 33 and the finger cutout 37. The shaft 10 and sheath 32 slidably extend through the sleeve 33 and between the rails 35a, 35b. The tube 17 also extends through the sleeve 33 and between the rails 35a, 35b, and its proximal end is fixed to the handle rail 35 near the finger cutout 37.

A compression spring 39 is disposed around the proximal most portion of the suction/insufflation tube 17 which lies between the rails 35a, 35b. One end of the compression spring 39 rests against the collar 13 on the shaft 10, while the opposite end of the compression spring rests against the handle rail 35. During

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use, the sheath 32 is retracted from the electrode carrying means 12 by squeezing the handle 34 towards the finger cutout 37 to slide the sheath 32 in the distal direction. When the handle 34 advances against the collar 13, the shaft 10 (which is attached to the collar 13) is forced to slide in the proximal direction, causing compression of the spring 39 against the handle rail 35. The movement of the shaft 10 relative to the suction/insufflation tube 17 causes the shaft 10 to pull proximally on the passive spring member 15. Proximal movement of the passive spring member 15 in turn pulls against the active spring member 19, causing it to move to the opened condition shown in Fig. 7. Unless the shaft is held in this retracted condition, the compression spring 39 will push the collar and thus the shaft distally, forcing the RF applicator head to close. A locking mechanism (not shown) may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the ablation procedure.

The amount by which the springs 15, 19 are spread may be controlled by manipulating the handle 34 to slide the shaft 10 (via collar 13), proximally or distally. Such sliding movement of the shaft 10 causes forceps-like movement of the spring members 15, 19.

A flow pathway 36 is formed in the handle rail 35 and is fluidly coupled to a suction/insufflation port 38. The proximal end of the suction/insufflation tube 17 is fluidly coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube 17 via the suction/insufflation port 38. For example, suction may be applied to the fluid port 38 using a

suction/insufflation unit 40. This causes water vapor within the uterine cavity to pass through the permeable electrode carrying means 12, into the suction/insufflation tube 17 via holes 17a, through the tube 17, and through the suction/insufflation unit 40 via the port 38. If insufflation of the uterine cavity is desired, insufflation gas, such as carbon dioxide, may be introduced into the suction/insufflation tube 17 via the port 38. The insufflation gas travels through the tube 17, through the holes 17a, and into the uterine cavity through the permeable electrode carrying member 12.

If desirable, additional components may be provided for endoscopic visualization purposes. For example, lumen 42, 44, and 46 may be formed in the walls of the introducer sheath 32 as shown in Fig. 5B. An imaging conduit, such as a fiberoptic cable 48, extends through lumen 42 and is coupled via a camera cable 43 to a camera 45. Images taken from the camera may be displayed on a monitor 56. An illumination fiber 50 extends through lumen 44 and is coupled to an illumination source 54. The third lumen 46 is an instrument channel through which surgical instruments may be introduced into the uterine cavity, if necessary.

Because during use it is most desirable for the electrodes 14 on the surface of the electrode carrying means 12 to be held in contact with the interior surface of the organ to be ablated, the electrode carrying means 12 may be provide to have additional components inside it that add structural integrity to the electrode carrying means when it is deployed within the body.

For example, referring to Fig. 11, alternative spring members 15a, 19a may be attached to the shaft 10 and biased such that,

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when in a resting state, the spring members are positioned in the fully resting condition shown in Fig. 11. Such spring members would spring to the resting condition upon withdrawal of the sheath 32 from the RF applicator head 2.

5 Alternatively, a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in Fig. 20 and connected to a tube (not shown) extending through the shaft 10 and into the balloons 52. After insertion of the apparatus into the organ and following retraction of the sheath 32, the balloons 52 would be
10 inflated by introduction of an inflation medium such as air into the balloons via a port similar to port 38 using an apparatus similar to the suction/insufflation apparatus 40.

 Structural integrity may also be added to the electrode
15 carrying means through the application of suction to the proximal end 22 of the suction/insufflation tube 17. Application of suction using the suction/insufflation device 40 would draw the organ tissue towards the electrode carrying means 12 and thus into better
20 contact with the electrodes 14.

 Figs. 12 and 13 show an alternative embodiment of an
20 ablation device according to the present invention. In the alternative embodiment, an electrode carrying means 12a is provided which has a shape which is generally tubular and thus is not specific to any particular organ shape. An ablation device having a general shape
25 such as this may be used anywhere within the body where ablation or coagulation is needed. For example, the alternative embodiment is useful for bleeding control during laparoscopic surgery (Fig. 14),

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tissue ablation in the prostate gland (Fig. 17), and also intrauterine ablation (Figs. 15 and 16).

First Exemplary Embodiment - Operation

Operation of the first exemplary embodiment of an ablation device according to the present invention will next be described.

Referring to Fig. 1, the device is initially configured for use by positioning the introducer sheath 32 distally along the shaft 10, such that it compresses the electrode carrying means 12 within its walls.

At this time, the electrical connector 21 is connected to the RF generator 16, and the fiberoptic cable 48 and the illumination cable 50 are connected to the illumination source, monitor, and camera, 54, 56, 45. The suction/insufflation unit 40 is attached to suction/insufflation port 38 on the handle rail 35. The suction/insufflation unit 40 is preferably set to deliver carbon dioxide at an insufflation pressure of 20 - 200 mmHg.

Next, the distal end of the apparatus is inserted through the vaginal opening V and into the uterus U as shown in Fig. 6, until the distal end of the introducer sheath 32 contacts the fundus F of the uterus. At this point, carbon dioxide gas is introduced into the tube 17 via the port 38, and it enters the uterine cavity, thereby expanding the uterine cavity from a flat triangular shape to a 1-2 cm high triangular cavity. The physician may observe (using the camera 45 and monitor 56) the internal cavities using images detected by a fiberoptic cable 48 inserted through lumen 42. If, upon observation, the physician determines that a tissue biopsy or other procedure is

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needed, the required instruments may be inserted into the uterine cavity via the instrument channel 46.

Following insertion, the handle 34 is withdrawn until it abuts the collar 13. At this point, the sheath 32 exposes the electrode carrying member 12 but the electrode carrying member 12 is not yet fully expanded (see Fig 9), because the spring members 15, 19 have not yet been moved to their open condition. The handle 34 is withdrawn further, causing the shaft 10 to move proximally relative to the suction/insufflation tube 17, causing the passive spring members 15 to pull the active spring members 19, causing them to open into the opened condition shown in Fig. 10.

The physician may confirm proper positioning of the electrode carrying member 12 using the monitor 56, which displays images from the fiberoptic cable 48.

Proper positioning of the device and sufficient contact between the electrode carrying member 12 and the endometrium may further be confirmed using the contact sensors 25a, 25b. The monitoring module of the RF generator measures the impedance between these sensors using conventional means. If there is good contact between the sensors and the endometrium, the measured impedance will be approximately 20 - 180 ohm, depending on the water content of the endometrial lining.

The sensors are positioned on the distal portions of the bicornual shaped electrode carrying member 12, which during use are positioned in the regions within the uterus in which it is most difficult to achieve good contact with the endometrium. Thus, an indication from the sensors 25a, 25b that there is sound contact

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between the sensors and the endometrial surface indicates that good electrode contact has been made with the endometrium.

Next, insufflation is terminated. Approximately 1 - 5 cc of saline may be introduced via suction/insufflation tube 17 to initially wet the electrodes and to improve electrode electrical contact with the tissue. After introduction of saline, the suction/insufflation device 40 is switched to a suctioning mode. As described above, the application of suction to the RF applicator head 2 via the suction/insufflation tube 17 collapses the uterine cavity onto the RF applicator head 2 and thus assures better contact between the electrodes and the endometrial tissue.

If the generally tubular apparatus of Figs. 12 and 13 is used, the device is angled into contact with one side of the uterus during the ablation procedure. Once ablation is completed, the device (or a new device) is repositioned in contact with the opposite side and the procedure is repeated. See. Figs. 15 and 16.

Next, RF energy at preferably about 500 kHz and at a constant power of approximately 30 W is applied to the electrodes. As shown in Fig. 5a, it is preferable that each electrode be energized at a polarity opposite from that of its neighboring electrodes. By doing so, energy field patterns, designated F1, F2 and F4 in Fig. 18, are generated between the electrode sites and thus help to direct the flow of current through the tissue T to form a region of ablation A. As can be seen in Fig. 18, if electrode spacing is increased such by energizing, for example every third or fifth electrode rather than all electrodes, the energy patterns will extend more deeply into the tissue. (See, for example, pattern F2 which results from

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energization of electrodes having a non-energized electrode between them, or pattern F4 which results from energization of electrodes having two non-energized electrodes between them).

Moreover, ablation depth may be controlled as described above by providing low surface density electrodes on areas of the electrode carrying member which will contact tissue areas at which a smaller ablation depth is required (see Fig. 19A). Referring to Fig. 19B, if multiple, closely spaced, electrodes 14 are provided on the electrode carrying member, a user may set the RF generator to energize electrodes which will produce a desired electrode spacing and active electrode area. For example, alternate electrodes may be energized as shown in Fig. 19B, with the first three energized electrodes having positive polarity, the second three having negative polarity, etc.

As another example, shown in Fig. 19C, if greater ablation depth is desired the first five electrodes may be positively energized, and the seventh through eleventh electrodes negatively energized, with the sixth electrode remaining inactivated to provide adequate electrode spacing.

As the endometrial tissue heats, moisture begins to be released from the tissue. The moisture permeates the electrode carrying member 12 and is thereby drawn away from the electrodes. The moisture may pass through the holes 17a in the suction/insufflation tube 17 and leave the suction/insufflation tube 17 at its proximal end via port 38 as shown in Fig. 7. Moisture removal from the ablation site may be further facilitated by the

application of suction to the shaft 10 using the suction/insufflation unit 40.

Removal of the moisture from the ablation site prevents formation of a liquid layer around the electrodes. As described above, liquid build-up at the ablation site is detrimental in that provides a conductive layer that carries current from the electrodes even when ablation has reached the desired depth. This continued current flow heats the liquid and surrounding tissue, and thus causes ablation to continue by unpredictable thermal conduction means.

Tissue which has been ablated becomes dehydrated and thus decreases in conductivity. By shunting moisture away from the ablation site and thus preventing liquid build-up, there is no liquid conductor at the ablation area during use of the ablation device of the present invention. Thus, when ablation has reached the desired depth, the impedance at the tissue surface becomes sufficiently high to stop or nearly stop the flow of current into the tissue. RF ablation thereby stops and thermal ablation does not occur in significant amounts. If the RF generator is equipped with an impedance monitor, a physician utilizing the ablation device can monitor the impedance at the electrodes and will know that ablation has self-terminated once the impedance rises to a certain level and then remains fairly constant. By contrast, if a prior art bipolar RF ablation device was used together with an impedance monitor, the presence of liquid around the electrodes would cause the impedance monitor to give a low impedance reading regardless of the depth of ablation which had already been carried out, since current would continue to travel through the low-impedance liquid layer.

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Other means for monitoring and terminating ablation may also be provided. For example, a thermocouple or other temperature sensor may be inserted to a predetermined depth in the tissue to monitor the temperature of the tissue and terminate the delivery of RF energy or otherwise signal the user when the tissue has reached a desired ablation temperature.

Once the process has self terminated, 1 - 5 cc of saline can be introduced via suction/insufflation tube 17 and allowed to sit for a short time to aid separation of the electrode from the tissue surface. The suction/insufflation device 40 is then switched to provide insufflation of carbon dioxide at a pressure of 20 - 200 mmHg. The insufflation pressure helps to lift the ablated tissue away from the RF applicator head 2 and to thus ease the closing of the RF applicator head. The RF applicator head 2 is moved to the closed position by sliding the handle 34 in a distal direction to fold the spring members 15, 19 along the axis of the device and to cause the introducer sheath 32 to slide over the folded RF applicator head. The physician may visually confirm the sufficiency of the ablation using the monitor 56. Finally, the apparatus is removed from the uterine cavity.

Second Exemplary Embodiment - Structure

A second embodiment of an ablation device 100 in accordance with the present invention is shown in Figs. 21 - 37B. The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array. Naturally, aspects of the first and

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second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.

Referring to Figs. 21 and 22, the second embodiment includes an RF applicator head 102, a sheath 104, and a handle 106. As with the first embodiment, the applicator head 102 is slidably disposed within the sheath 104 (Fig. 21) during insertion of the device into the uterine cavity, and the handle 106 is subsequently manipulated to cause the applicator head 102 to extend from the distal end of the sheath 104 (Fig. 22) and to expand into contact with body tissue (Fig. 33).

RF Applicator Head

Referring to Fig. 23, in which the sheath 104 is not shown for clarity, applicator head 102 extends from the distal end of a length of tubing 108 which is slidably disposed within the sheath 104. Applicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue.

Referring to Figs. 25A and 25B, the array 102a of applicator head 102 is formed of a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material. In one array design, the knit (shown in Figs. 26A and 26B) is formed of three monofilaments of nylon 109a knitted together with single yarns of spandex 109b. Each yarn of spandex 109b has a double helix 109c of five nylon monofilaments coiled around it.

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This knit of elastic (spandex) and inelastic (nylon) yarns is beneficial for a number of reasons. For example, knitting elastic and relatively inelastic yarns allows the overall deformability of the array to be pre-selected.

5 The mesh is preferably constructed so as to have greater elasticity in the transverse direction (T) than in the longitudinal direction (L). In a preferred mesh design, the transverse elasticity is on the order of approximately 300% whereas the longitudinal elasticity is on the order of approximately 100%. The large
10 transverse elasticity of the array allows it to be used in a wide range of uterine sizes.

 Another advantage provided by the combination of elastic and relatively inelastic yarns is that the elastic yarns provide the needed elasticity to the array while the relatively inelastic yarns provide
15 relatively non-stretchable members to which the metallization can adhere without cracking during expansion of the array. In the knit configuration described above, the metallization adheres to the nylon coiled around the spandex. During expansion of the array, the spandex elongates and the nylon double helix at least partially
20 elongates from its coiled configuration.

 One process which may be used to apply the gold to the nylon/spandex knit involves plating the knit with silver using known processes which involve application of other materials as base layers prior to application of the silver to ensure that the silver will adhere.
25 Next, the insulating regions 110 (described below) are etched onto the silver, and afterwards the gold is plated onto the silver. Gold is desirable for the array because of it has a relatively smooth surface,

is a very inert material, and has sufficient ductility that it will not crack as the nylon coil elongates during use.

The mesh may be configured in a variety of shapes, including but not limited to the triangular shape S1, parabolic S2, and rectangular S3 shapes shown in Figs. 27A, 27B and 27C, respectively.

Turning again to Figs. 25A and 25B, when in its expanded state, the array 102a includes a pair of broad faces 112 spaced apart from one another. Narrower side faces 114 extend between the broad faces 112 along the sides of the applicator head 102, and a distal face 116 extends between the broad faces 112 at the distal end of the applicator head 102.

Insulating regions 110 are formed on the applicator head to divide the mesh into electrode regions. The insulated regions 110 are preferably formed using etching techniques to remove the conductive metal from the mesh, although alternate methods may also be used, such as by knitting conductive and non-conductive materials together to form the array.

The array may be divided by the insulated regions 110 into a variety of electrode configurations. In a preferred configuration the insulating regions 110 divide the applicator head into four electrodes 118a - 118d by creating two electrodes on each of the broad faces 112. To create this four-electrode pattern, insulating regions 110 are placed longitudinally along each of the broad faces 112 as well as along the length of each of the faces 114, 116. The electrodes 118a-118d are used for ablation and, if desired, to measure tissue impedance during use.

Deflecting mechanism 102b and its deployment structure is enclosed within electrode array 102a. Referring to Fig. 23, external hypotube 120 extends from tubing 108 and an internal hypotube 122 is slidably and co-axially disposed within hypotube 120.

5 Flexures 124 extend from the tubing 108 on opposite sides of external hypotube 120. A plurality of longitudinally spaced apertures 126 (Fig. 28) are formed in each flexure 124. During use, apertures 126 allow moisture to pass through the flexures and to be drawn into exposed distal end of hypotube 120 using a vacuum
10 source fluidly coupled to hypotube 120.

Each flexure 124 preferably includes conductive regions that are electrically coupled to the array 102a for delivery of RF energy to the body tissue. Referring to Fig. 29, strips 128 of copper tape or other conductive material extend along opposite surfaces of each
15 flexure 124. Each strip 128 is electrically insulated from the other strip 128 by a non-conductive coating on the flexure. Conductor leads (not shown) are electrically coupled to the strips 128 and extend through tubing 108 (Fig. 23) to an electrical cord 130 (Fig. 21) which is attachable to the RF generator.

20 During use, one strip 128 on each conductor is electrically coupled via the conductor leads to one terminal on the RF generator while the other strip is electrically coupled to the opposite terminal, thus causing the array on the applicator head to have regions of alternating positive and negative polarity.

25 The flexures may alternatively be formed using a conductive material or a conductively coated material having insulating regions formed thereon to divide the flexure surfaces into multiple

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conductive regions. Moreover, alternative methods such as electrode leads independent of the flexures 124 may instead be used for electrically connecting the electrode array to the source of RF energy.

5 It is important to ensure proper alignment between the conductive regions of the flexures 124 (e.g. copper strips 128) and the electrodes 118a - 118d in order to maintain electrical contact between the two. Strands of thread 134 (which may be nylon) (Fig. 23) are preferably sewn through the array 102a and around the
10 flexures 124 in order to prevent the conductive regions 128 from slipping out of alignment with the electrodes 118a - 118d. Alternate methods for maintaining contact between the array 102a and the conductive regions 128 include using tiny bendable barbs extending between the flexures 124 and the array 102a to hook the array to
15 the conductive regions 128, or bonding the array to the flexures using an adhesive applied along the insulating regions of the flexures.

Referring again to Fig. 23, internal flexures 136 extend laterally and longitudinally from the exterior surface of hypotube
20 122. Each internal flexure 136 is connected at its distal end to one of the flexures 124 and a transverse ribbon 138 extends between the distal portions of the internal flexures 136. Transverse ribbon 138 is preferably pre-shaped such that when in the relaxed condition the ribbon assumes the corrugated configuration shown in Fig. 23
25 and such that when in a compressed condition it is folded along the plurality of creases 140 that extend along its length. Flexures 124,

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136 and ribbon 138 are preferably an insulated spring material such as heat treated 17-7 PH stainless steel.

5 The deflecting mechanism is preferably configured such that the distal tips of the flexures 124 are sufficiently flexible to prevent tissue puncture during deployment and/or use. Such an atraumatic tip design may be carried out in a number of ways, such as by manufacturing the distal sections 124a (Fig. 28) of the flexures from a material that is more flexible than the proximal sections 124b. For example, flexures 124 may be provided to have proximal
10 sections formed of a material having a modulus of approximately 28×10^6 psi and distal sections having a durometer of approximately 72D.

Alternatively, referring to Fig. 30, the flexures 124 may be joined to the internal flexures 136 at a location more proximal than the distal tips of the flexures 124, allowing them to move more
15 freely and to adapt to the contour of the surface against which they are positioned (see dashed lines in Fig. 30). Given that uterine sizes and shapes vary widely between women, the atraumatic tip design is further beneficial in that it allows the device to more accurately
20 conform to the shape of the uterus in which it is deployed while minimizing the chance of injury.

25 The deflecting mechanism formed by the flexures 124, 136, and ribbon 138 forms the array into the substantially triangular shape shown in Fig. 23, which is particularly adaptable to most uterine shapes. As set forth in detail below, during use distal and proximal grips 142, 144 forming handle 106 are squeezed towards one another to withdraw the sheath and deploy the applicator head.

This action results in relative rearward motion of the hypotube 120 and relative forward motion of the hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102a.

5 *Measurement Device*

 The ablation device according to the second embodiment includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge 146 (Fig. 21). The measurement device utilizes non-conductive (e.g. nylon) suturing threads 148 that extend from the hypotube 122 and that have distal ends attached to the distal portion of the deflecting mechanism (Fig. 23). As shown in Fig. 24, threads 148 are preferably formed of a single strand 150 threaded through a wire loop 152 and folded over on itself. Wire loop 152 forms the distal end of an elongate wire 154 which may be formed of stainless steel or other wire.

 Referring to Fig. 31, wire 154 extends through the hypotube 122 and is secured to a rotatable bobbin 156. The rotatable bobbin 156 includes a dial face 158 preferably covered in a clear plastic. As can be seen in Fig. 32, dial face 158 includes calibration markings corresponding to an appropriate range of uterine widths. The bobbin is disposed within a gauge housing 160 and a corresponding marker line 162 is printed on the gauge housing. A torsion spring 164 provides rotational resistance to the bobbin 156.

25 Expansion of the applicator head 102 during use pulls threads 148 (Fig. 23) and thus wire 154 (Fig. 24) in a distal direction. Wire 154 pulls against the bobbin 156 (Fig. 31), causing it to rotate.

Rotation of the bobbin positions one of the calibration markings on dial face 158 into alignment with the marker line 162 (Fig. 32B) to indicate the distance between the distal tips of flexures 124 and thus the uterine width.

5 The uterine width and length (as determined using a conventional sound or other means) are preferably input into an RF generator system and used by the system to calculate an appropriate ablation power as will be described below. Alternately, the width as measured by the apparatus of the invention and length as measured
10 by other means may be used by the user to calculate the power to be supplied to the array to achieve the desired ablation depth.

 The uterine width may alternatively be measured using other means, including by using a strain gauge in combination with an A/D converter to transduce the separation distance of the flexures 124
15 and to electronically transmit the uterine width to the RF generator.

Control of Ablation Depth

 The most optimal electrocoagulation occurs when relatively deep ablation is carried out in the regions of the uterus at which the endometrium is thickest, and when relatively shallower ablation is
20 carried out in areas in which the endometrium is shallower. A desirable range of ablation depths includes approximately 2 - 3 mm for the cervical os and the cornual regions, and approximately 7 - 8 mm in the main body of the uterus where the endometrium is substantially thicker.

25 As discussed with respect to the first embodiment, a number of factors influence the ablation depth that can be achieved using a

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given power applied to a bipolar electrode array. These include the power supplied by the RF generator, the distance between the centers of adjacent electrodes ("center-to-center distance"), the electrode density (i.e., the porosity of the array fabric or the percent of the array surface that is metallic), the edge gap (i.e. the distance between the edges of adjacent electrode poles), and the electrode surface area. Other factors include blood flow (which in slower-ablating systems can dissipate the RF) and the impedance limit.

Certain of these factors may be utilized in the present invention to control ablation depth and to provide deeper ablation at areas requiring deeper ablation and to provide shallower regions in areas where deep ablation is not needed. For example, as center-to-center distance increases, the depth of ablation increases until a point where the center to center distance is so great that the strength of the RF field is too diffuse to excite the tissue. It can be seen with reference to Fig. 33 that the center to center distance d1 between the electrodes 118a, 118b is larger within the region of the array that lies in the main body of the uterus and thus contributes to deeper ablation. The center to center distance d2 between electrodes 118a, 118b is smaller towards the cervical canal where it contributes to shallower ablation. At the distal end of the device, the shorter center to center distances d3 extend between top and bottom electrodes 118b, 118c and 118a, 118d and again contribute to shallower ablation.

Naturally, because the array 102a expands to accommodate the size of the uterus in which it is deployed, the dimensions of the array 102a vary. One embodiment of the array 102a includes a

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range of widths of at least approximately 2.5 - 4.5 cm, a range of lengths of at least approximately 4 -6 cm, and a density of approximately 35% - 45%.

5 The power supplied to the array by the RF generator is calculated by the RF generator system to accommodate the electrode area required for a particular patient. As discussed above, the uterine width is measured by the applicator head 102 and displayed on gauge 146. The uterine length is measured using a sound, which is an instrument conventionally used for that purpose. 10 It should be noted that calibration markings of the type used on a conventional sound device, or other structure for length measurement, may be included on the present invention to allow it to be used for length measurement as well.

15 The user enters the measured dimensions into the RF generator system using an input device, and the RF generator system calculates or obtains the appropriate set power from a stored look-up table using the uterine width and length as entered by the user. An EPROM within the RF generator system converts the length and width to a set power level according to the following 20 relationship:

$$P = L \times W \times 5.5$$

Where P is the power level in watts, L is the length in centimeters, W is the width in centimeters, and 5.5 is a constant having units of watts per square centimeter.

Alternatively, the user may manually calculate the power setting from the length and width, or s/he may be provided with a table of suggested power settings for various electrode areas (as determined by the measured length and width) and will manually set the power on the RF generator accordingly.

Handle

Referring again to Figs. 21 and 22, the handle 106 of the RF ablation device according to the second embodiment includes a distal grip section 142 and a proximal grip section 144 that are pivotally attached to one another at pivot pin 166.

The proximal grip section 144 is coupled to the hypotube 122 (Fig. 23) via yoke 168, overload spring 170 and spring stop 172, each of which is shown in the section view of Fig. 34. The distal grip section 142 is coupled to the external hypotube 120 via male and female couplers 174, 176 (see Figs. 32A and 32B). Squeezing the grip sections 142, 144 towards one another thus causes relative movement between the external hypotube 120 and the internal hypotube 122. This relative sliding movement results in deployment of the deflecting mechanism 102b from the distal end of the sheath and expansion of the array 102a to its expanded state.

Referring to Figs. 32A and B, rack 180 is formed on male coupler 174 and calibration markings 182 are printed adjacent the rack 180. The calibration markings 182 correspond to a variety of uterine lengths and may include lengths ranging from, for example, 4.0 to 6.0 cm in 0.5 cm increments.

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A sliding collar 184 is slidably disposed on the tubing 108 and is slidable over male coupler 174. Sliding collar 184 includes a rotating collar 186 and a female coupler 176 that includes a wedge-shaped heel 188. A locking spring member 190 (Figs. 32B and 35) extends across an aperture 192 formed in the proximal grip 144 in alignment with the heel 188. When the distal and proximal handle sections are squeezed together to deploy the array, the heel 188 passes into the aperture 192. Its inclined lower surface gradually depresses the spring member 190 as the heel moves further into the aperture 192. See Figs. 36A and 36B. After passing completely over the spring member, the heel moves out of contact with the spring member. The spring member snaps upwardly thereby engaging the heel in the locked position. See Fig. 36C.

A release lever 194 (Fig. 35) is attached to the free end of the spring member 190. To disengage the spring lock, release lever 194 is depressed to lower spring member 190 so that the inclined heel can pass over the spring member and thus out of the aperture 192.

Referring again to Figs. 32A and 32B, sliding collar 184 is configured to allow the user to limit longitudinal extension of the array 102a to a distance commensurate with a patient's predetermined uterine length. It does so by allowing the user to adjust the relative longitudinal position of male coupler 174 relative to the female coupler 176 using the rotating collar 186 to lock and unlock the female coupler from the rack 180 and the male coupler 174. Locking the female coupler to the rack 180 and male coupler 174 will limit extension of the array to approximately the

predetermined uterine length, as shown on the calibration markings 182.

Once the uterine length has been measured using a conventional sound, the user positions sliding collar 184 adjacent to calibration marks 182 corresponding to the measured uterine length (e.g. 4.5 cm). Afterwards, the user rotates the collar section 186 to engage its internally positioned teeth with the rack 180. This locks the longitudinal position of the heel 188 such that it will engage with the spring member 190 on the proximal grip when the array has been exposed to the length set by the sliding collar.

The handle 106 includes a pair of spring assemblies which facilitate controlled deployment and stowage of the array 102a. One of the spring assemblies controls movement of the grips 142, 144 to automatically stow the array 102a into the sheath 104 when the user stops squeezing the grips 142, 144 towards one another. The other of the spring assemblies controls the transverse movement of the spring flexures 124 to the expanded condition by limiting the maximum load that can be applied to the deployment mechanism 102b.

Fig. 34 shows the distal and proximal grips 142 and 144 in partial cross-section. The first spring assembly for controlled stowage includes a handle return mandrel 196 that is slidably disposed within the proximal grip 144. A compression spring 198 surrounds a portion of the return mandrel 196, and a retaining ring 200 is attached to the mandrel 196 above the spring 198. A spring stop 202 is disposed between the spring 198 and the retaining ring.

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The lowermost end of the return mandrel 196 is pivotally engaged by a coupling member 204 on distal grip 142. Relative movement of the grips 142, 144 towards one another causes the coupling member 204 to pull the return member downwardly with the proximal grip 144 as indicated by arrows. Downward movement of the mandrel 196 causes its retaining ring 200 and spring stop 202 to bear downwardly against the compression spring 198, thereby providing a movement which acts to rotate the grips 142, 144 away from one another. When tension against the grips 142, 144 is released (assuming that heel 188 is not locked into engagement with spring member 190) the grips rotate apart into the opened position as the compression spring 198 returns to the initial state, stowing the applicator head inside the sheath.

The second spring assembly for controlling array deployment is designed to control separation of the flexures. It includes a frame member 178 disposed over yoke 168, which is pivotally attached to proximal grip 144. Tubing 108 extends from the array 102a (see Fig. 23), through the sheath 104 and is fixed at its proximal end to the frame member 178. Hypotube 122 does not terminate at this point but instead extends beyond the proximal end of tubing 108 and through a window 206 in the frame member. Its proximal end 208 is slidably located within frame member 178 proximally of the window 206 and is fluidly coupled to a vacuum port 210 by fluid channel 212. Hypotube 120 terminates within the frame. Its proximal end is fixed within the distal end of the frame.

A spring stop 214 is fixed to a section of the hypotube within the window 206, and a compression spring 170 is disposed around

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the hypotube between the spring stop 172 and yoke 168. See Figs. 32B and 34.

When the distal and proximal grips are moved towards one another, the relative rearward motion of the distal grip causes the distal grip to withdraw the sheath 104 from the array 102a. Referring to Figs. 37A and 37B, this motion continues until female coupler 176 contacts and bears against frame member 178. Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube 120. An opposing force is developed in yoke 168, which causes a relative forward motion in hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array. Compression spring 170 acts to limit the force developed by the operator against hypotubes 120, 122, thus limiting the force of flexures 124, 136 acting on the array and the target tissue surrounding the array.

Referring to Fig. 21, collar 214 is slidably mounted on sheath 104. Before the device is inserted into the uterus, collar 214 can be positioned along sheath 104 to the position measured by the uterine sound. Once in position, the collar provides visual and tactile feedback to the user to assure the device has been inserted the proper distance. In addition, after the applicator head 102 has been deployed, if the patient's cervical canal diameter is larger than the sheath dimensions, the collar 214 can be moved distally towards the cervix, making contact with it and creating a pneumatic seal between the sheath and cervix.

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Second Exemplary Embodiment - Operation

In preparation for ablating the uterus utilizing the second exemplary embodiment, the user measures the uterine length using a uterine sound device. The user next positions sliding collar 184 (Fig. 32B) adjacent to calibration marks 182 corresponding to the measured uterine length (e.g. 4.5 cm) and rotates the collar section 186 to engage its internally positioned teeth with the rack 180. This locks the longitudinal position of the heel 188 (Fig. 32A) such that it will engage with the spring member 190 when the array has been exposed to the length set by the sliding collar.

Next, with the grips 142, 144 in their resting positions to keep the applicator head 102 covered by sheath 104, the distal end of the device 100 is inserted into the uterus. Once the distal end of the sheath 104 is within the uterus, grips 142, 144 are squeezed together to deploy the applicator head 102 from sheath 104. Grips 142, 144 are squeezed until heel 188 engages with locking spring member 190 as described with respect to Figs. 36A through 36C.

At this point, deflecting mechanism 102b has deployed the array 102a into contact with the uterine walls. The user reads the uterine width, which as described above is transduced from the separation of the spring flexures, from gauge 146. The measured length and width are entered into the RF generator system 250 (Fig. 21) and used to calculate the ablation power.

Vacuum source 252 (Fig. 21) is activated, causing application of suction to hypotube 122 via suction port 210. Suction helps to draw uterine tissue into contact with the array 102.

Ablation power is supplied to the electrode array 102a by the RF generator system 250. The tissue is heated as the RF energy passes from electrodes 118a-d to the tissue, causing moisture to be released from the tissue. The vacuum source helps to draw moisture from the uterine cavity into the hypotube 122. Moisture withdrawal is facilitated by the apertures 126 formed in flexures 124 by preventing moisture from being trapped between the flexures 124 and the lateral walls of the uterus.

If the RF generator 250 includes an impedance monitoring module, impedance may be monitored at the electrodes 118a-d and the generator may be programmed to terminate RF delivery automatically once the impedance rises to a certain level. The generator system may also or alternatively display the measured impedance and allow the user to terminate RF delivery when desired.

When RF delivery is terminated, the user depresses release lever 194 to disengage heel 188 from locking spring member 190 and to thereby allow grips 142, 144 to move to their expanded (resting condition). Release of grips 142, 144 causes applicator head 102 to retract to its unexpanded condition and further causes applicator head 102 to be withdrawn into the sheath 104. Finally, the distal end of the device 100 is withdrawn from the uterus.

Two embodiments of ablation devices in accordance with the present invention have been described herein. These embodiments have been shown for illustrative purposes only. It should be understood, however, that the invention is not intended to be limited to the specifics of the illustrated embodiments but is defined only in terms of the following claims.

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We Claim:

1. A method of ablating and/or coagulating tissue,
comprising the steps of:

5 (a) providing an ablation device including an electrode array
carried by an elongate tubular member, the electrode array including
a fluid permeable elastic member having insulating regions and
conductive regions thereon;

(b) positioning the electrode array in contact with tissue to be
ablated;

10 (c) delivering RF energy through the array to the tissue to
cause the tissue to dehydrate; and

(d) permitting moisture generated during the dehydration of
step (c) to pass into the electrode carrying member and away from
the tissue.

15 2. The method of claim 1 wherein the fluid permeable
elastic member includes metallized fabric.

3. The method of claim 1 wherein the array is expandable
and wherein step (b) further includes the step of moving the array to
an expanded condition.

20 4. The method of claim 3 wherein the array is carried by a
pair of elongate flexures and wherein the step of moving the array to
the expanded condition includes the step of expanding the flexures.

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5. The method of claim 4 wherein each flexure includes at least one opening and wherein step (d) includes allowing at least a portion of the moisture to pass through the openings in the flexures.

5 6. The method of claim 1 wherein step (d) includes permitting at least a portion of the moisture to pass from the array into the tubular member.

7. The method of claim 3 wherein step (d) includes the step of applying suction to draw the moisture through the tubular member.

10 8. The method of claim 1 wherein the method further includes the step of

(e) monitoring impedance using the electrode array and automatically terminating the flow of current into the tissue once impedance has approximately reached a predetermined level.

15 9. The method of claim 1 wherein the method further includes the step of measuring the approximate length and width of the organ and wherein step (c) includes the steps of selecting an ablation power corresponding to the measured length and width and delivering the RF energy to the tissue at approximately the selected
20 power.

10. The method of claim 9 wherein the array is carried by a pair of elongate flexures and wherein the step of measuring the

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approximate width of the organ includes the step of expanding the flexures to an expanded condition and deriving the approximate width of the uterus from the relative positions of the flexures in the expanded condition.

5 11. The method of claim 9 wherein step (c) further includes selecting an ablation power which is proportional to the measured length times the measured width.

12. The method of claim 2 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

10 13. The method of claim 12 wherein the metallized fabric includes yarns of spandex and nylon.

15 14. The method of claim 2 wherein the array material has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

15. The method of claim 1 including the step of applying suction through the tubular member to draw the tissue into contact with the electrode array.

20 16. An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

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an electrode array carried by an elongate member, the array including a fluid permeable elastic member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array.

17. The ablation and/or coagulation apparatus of claim 16 further including an elongate tube having at least one opening adjacent to the array and a vacuum source fluidly coupled to the elongate tube.

18. The apparatus of claim 16 wherein the fluid permeable elastic member includes metallized fabric.

19. The apparatus of claim 18 wherein the metallized fabric includes yarns of elastic material and yarns of inelastic material.

20. The apparatus of claim 18 wherein the metallized fabric includes yarns of spandex and nylon.

21. The apparatus of claim 16 wherein the array has elasticity in a transverse direction and in a longitudinal direction and wherein the elasticity in the transverse direction is greater than the elasticity in the longitudinal direction.

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22. The apparatus of claim 16 wherein the electrode array is carried by a deflecting mechanism moveable between a retracted position and an expanded position.

5 23. The apparatus of claim 22 wherein the deflecting mechanism includes a pair of elongate flexures.

24. The apparatus of claim 23 wherein the flexures include at least one fluid opening.

10 25. The apparatus of claim 22 wherein the deflecting mechanism includes electrically conductive regions electrically coupled to conductive regions of the electrode array.

26. The apparatus of claim 23 wherein the flexures include electrically conductive regions electrically coupled to conductive regions of the electrode array.

15 27. The apparatus of claim 16 further comprising:
width measurement means for measuring the approximate width of the organ.

28. The apparatus of claim 27 further comprising:
length measurement means for measuring the approximate length of the organ.

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29. The apparatus of claim 27 further comprising means for determining an ablation power using the measured approximate width.

30. The apparatus of claim 28 further comprising means for determining an ablation power using the measured approximate width and length.

31. An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

an elongate member;

a deployment mechanism carried by the elongate member, the deployment mechanism moveable between a retracted position and a plurality of laterally expanded positions;

an electrode array carried by the deployment mechanism;

a sheath slidably disposed over the electrode array;

a handle coupled to the sheath and deployment mechanism, the handle moveable between an insertion position in which the sheath is disposed over the electrode array and the array is in an unexpanded condition, and a deployment position in which the electrode array extends from the distal end of the sheath and is in one of its expanded positions;

limiting means for selectively limiting lateral expansion of the deployment mechanism and for selectively limiting longitudinal extension of the array from the sheath; and

a source of radio frequency energy electrically coupled to the array.

PATENT APPLICATION

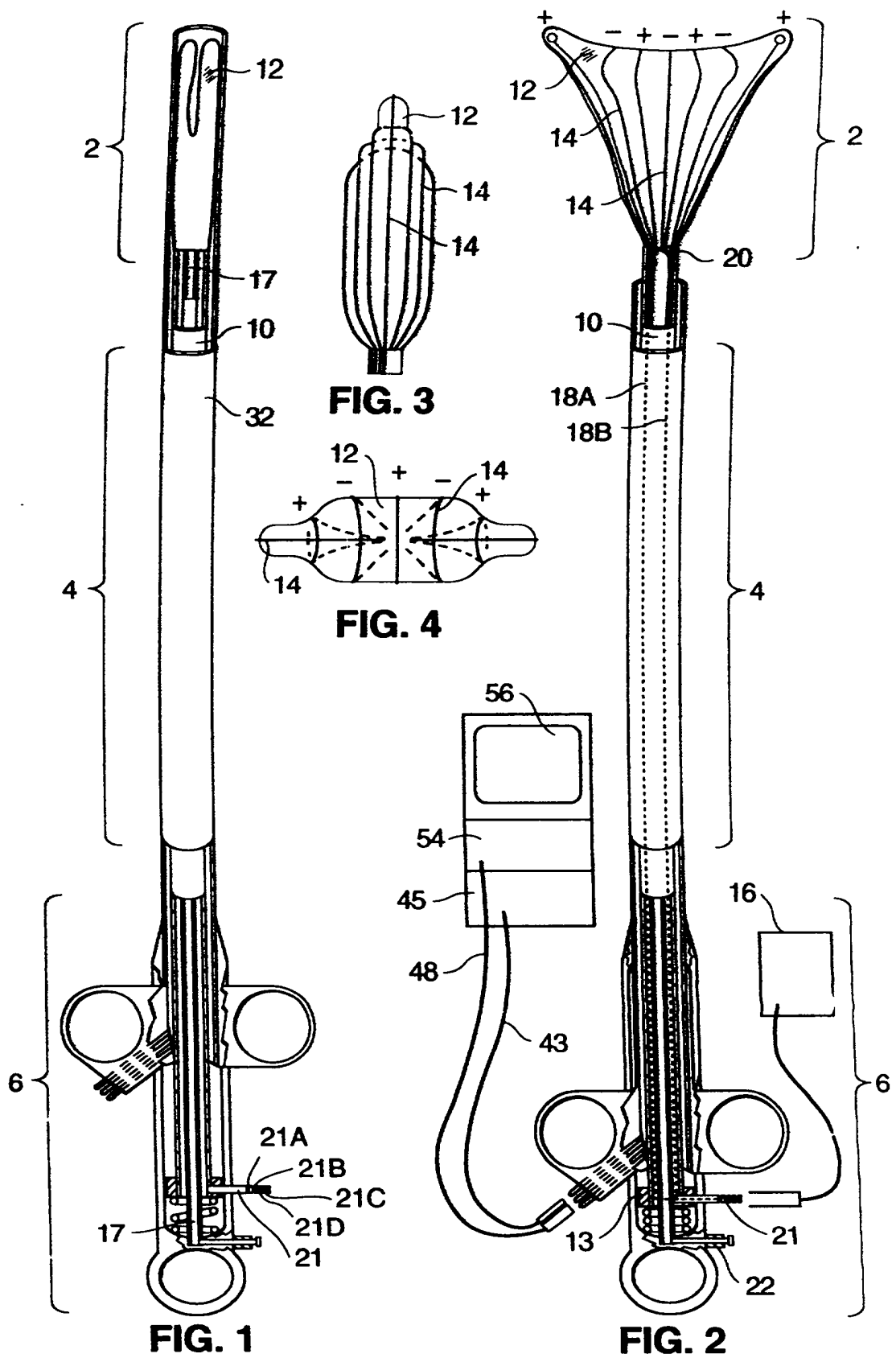
Express Mailing Label: EM503277278US

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ABSTRACT OF THE DISCLOSURE

An apparatus and method for use in performing ablation or coagulation of organs and other tissue includes a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to the body cavity. The array includes conductive regions separated by insulated regions arranged to produce ablation to a predetermined depth. Following placement of the ablation device into contact with the tissue to be ablated, an RF generator is used to deliver RF energy to the conductive regions and to thereby induce current flow from the electrodes to tissue to be ablated. As the current heats the tissue, moisture (such as steam or liquid) leaves the tissue causing the tissue to dehydrate. Suction may be applied to facilitate moisture removal. The moisture permeability and/or absorbency of the electrode carrying member allows the moisture to leave the ablation site so as to prevent the moisture from providing a path of conductivity for the current.

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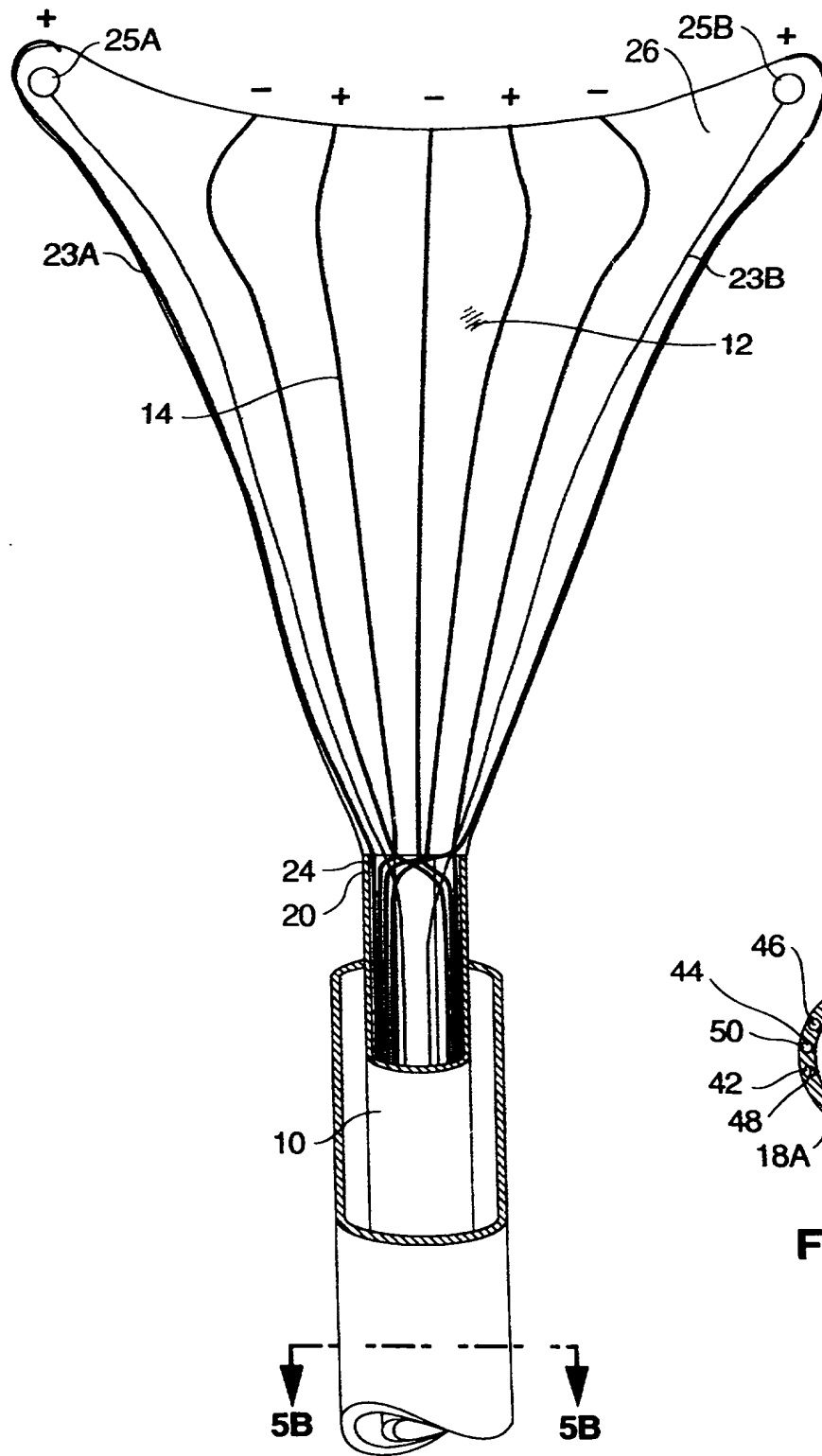


FIG. 5A

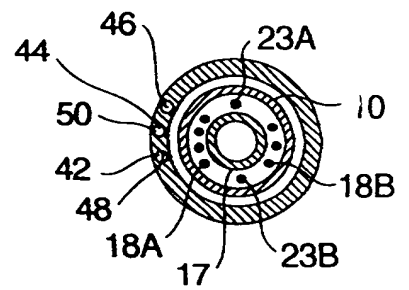


FIG. 5B

FIG. 1 is a schematic diagram of a medical device for treating a urinary tract condition. The device is inserted into the urethra and bladder. It features a central shaft (32) with a distal tip (17) and a proximal handle (34). A control unit (40) is connected to the device via a cable (38). The device is shown in a cross-sectional view, revealing internal components like a catheter (12) and a balloon (15).

FIG. 7

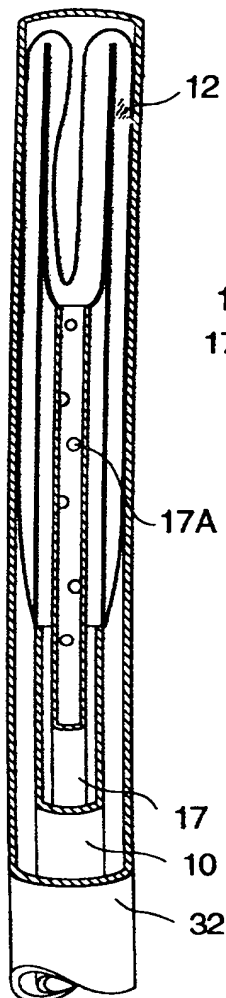


FIG. 8

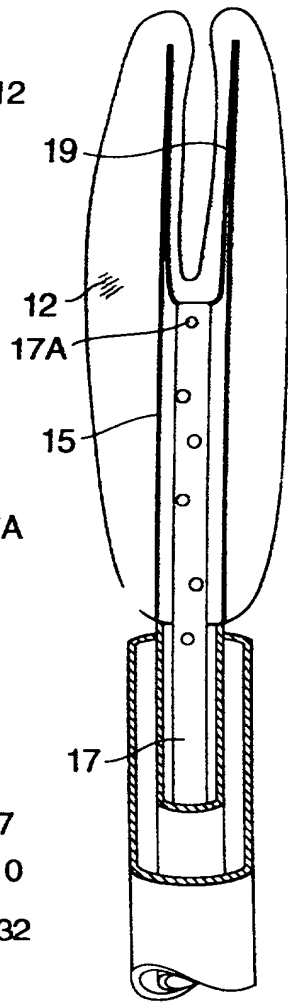


FIG. 9

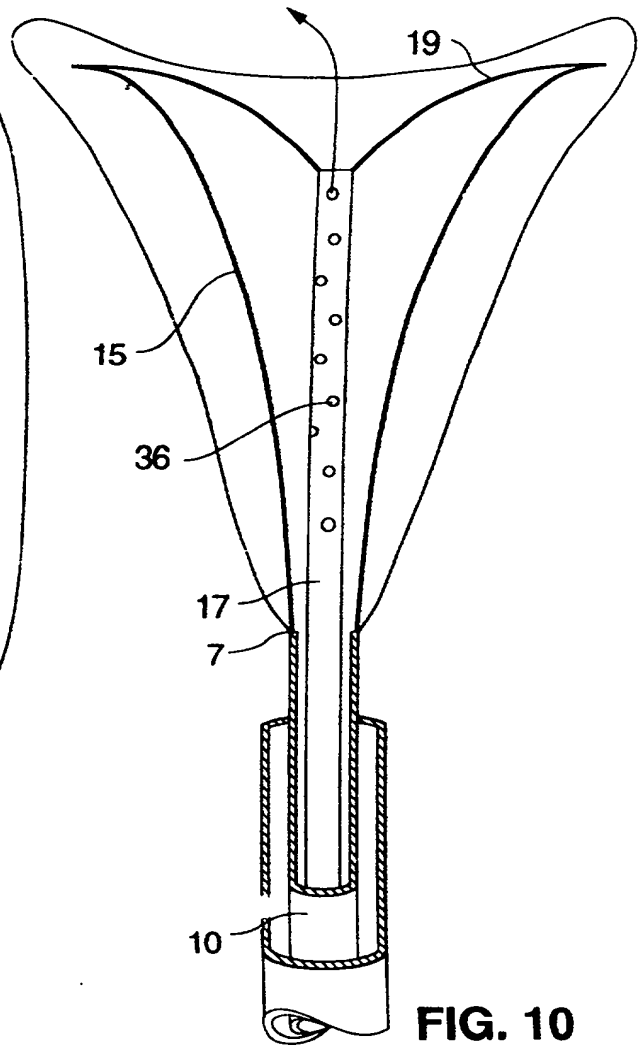


FIG. 10

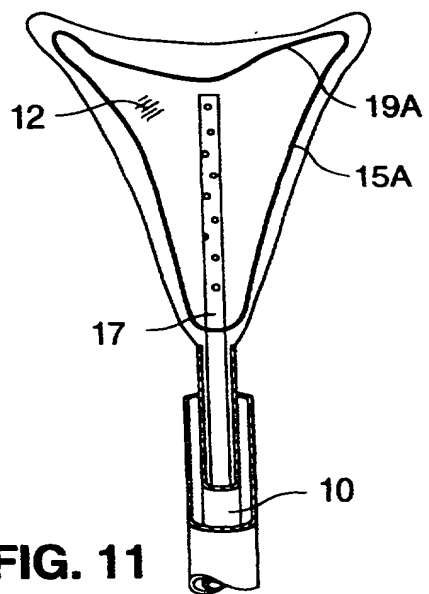


FIG. 11

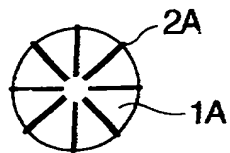


FIG. 13

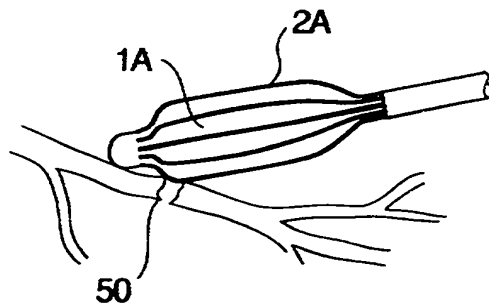


FIG. 14

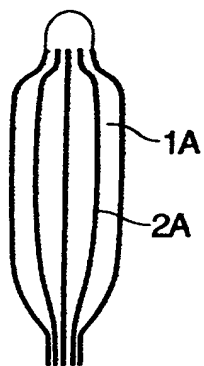


FIG. 12

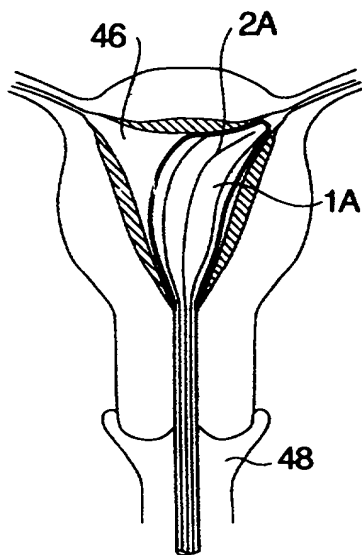


FIG. 15

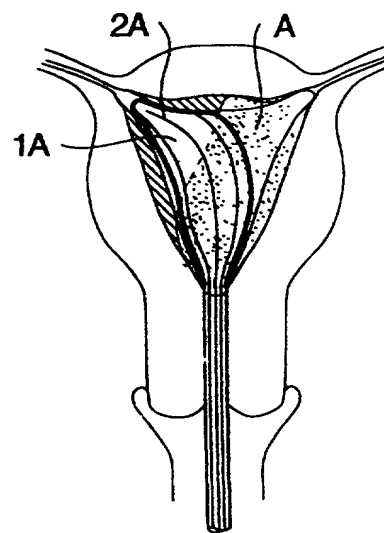


FIG. 16

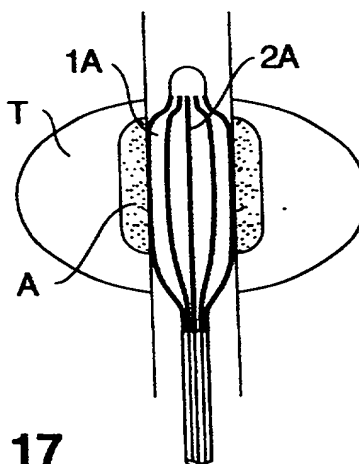


FIG. 17

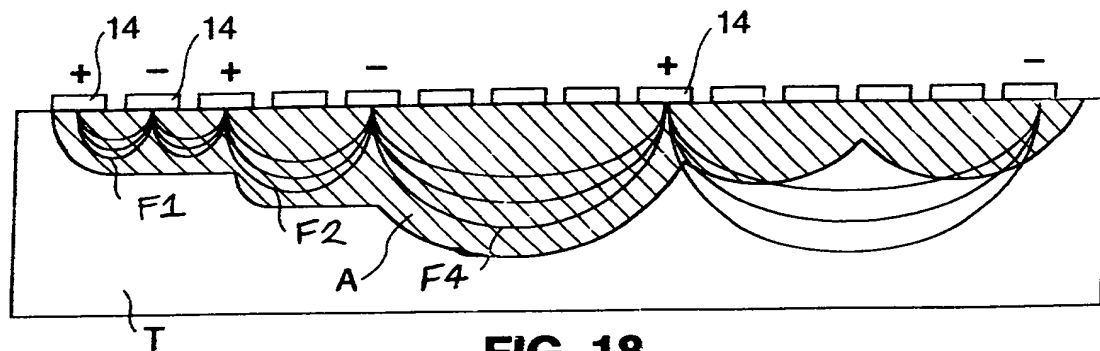


FIG. 18

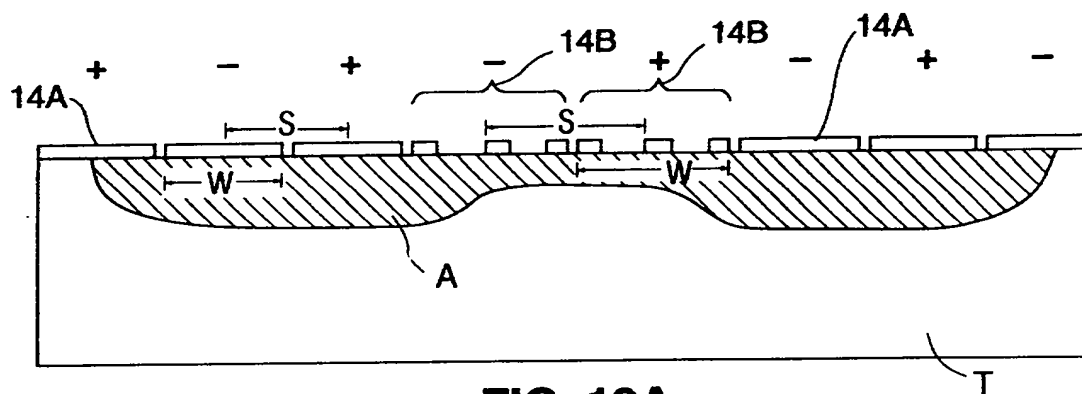


FIG. 19A

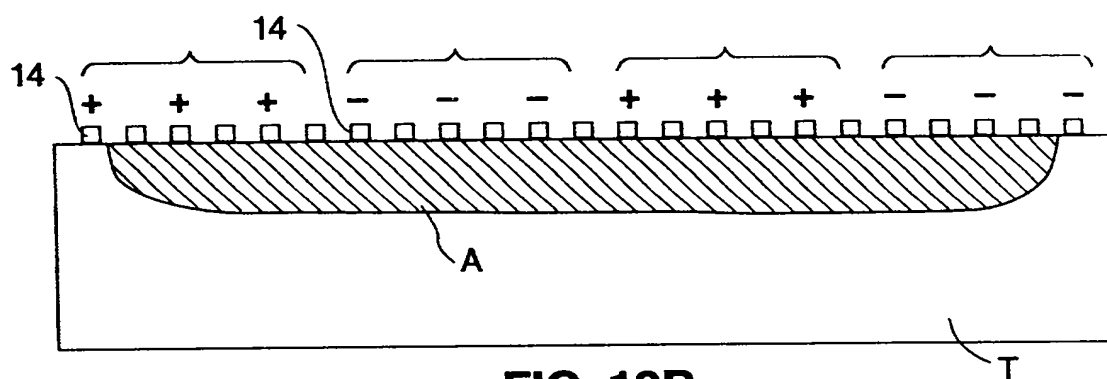


FIG. 19B

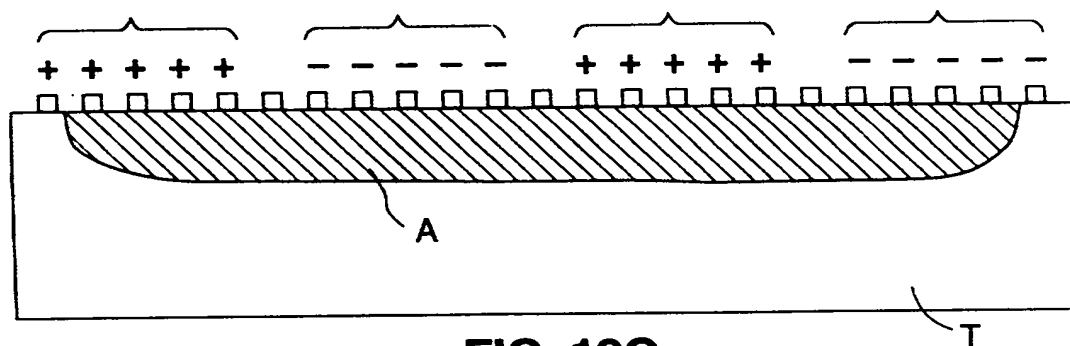


FIG. 19C

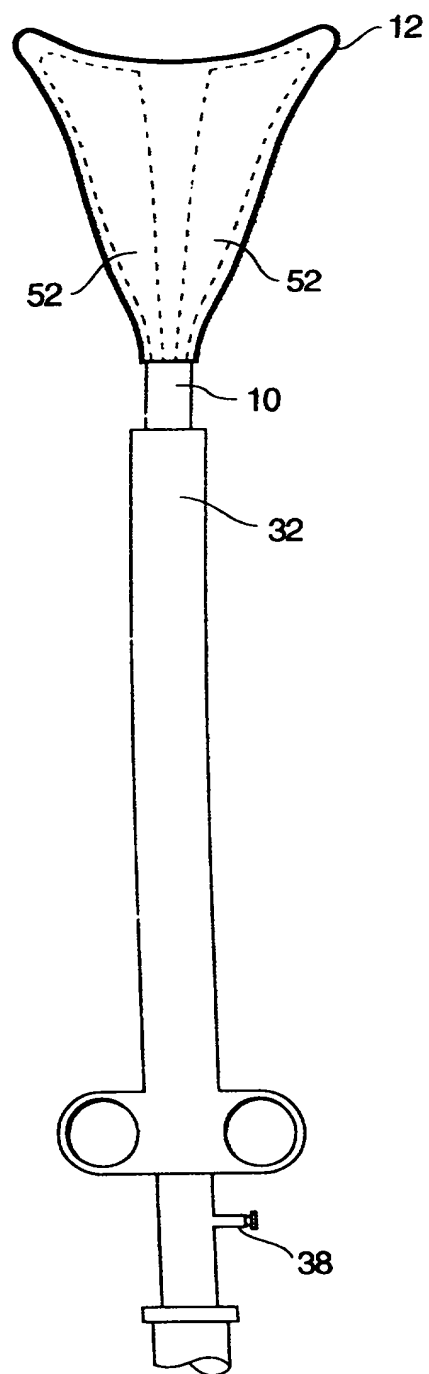


FIG. 20

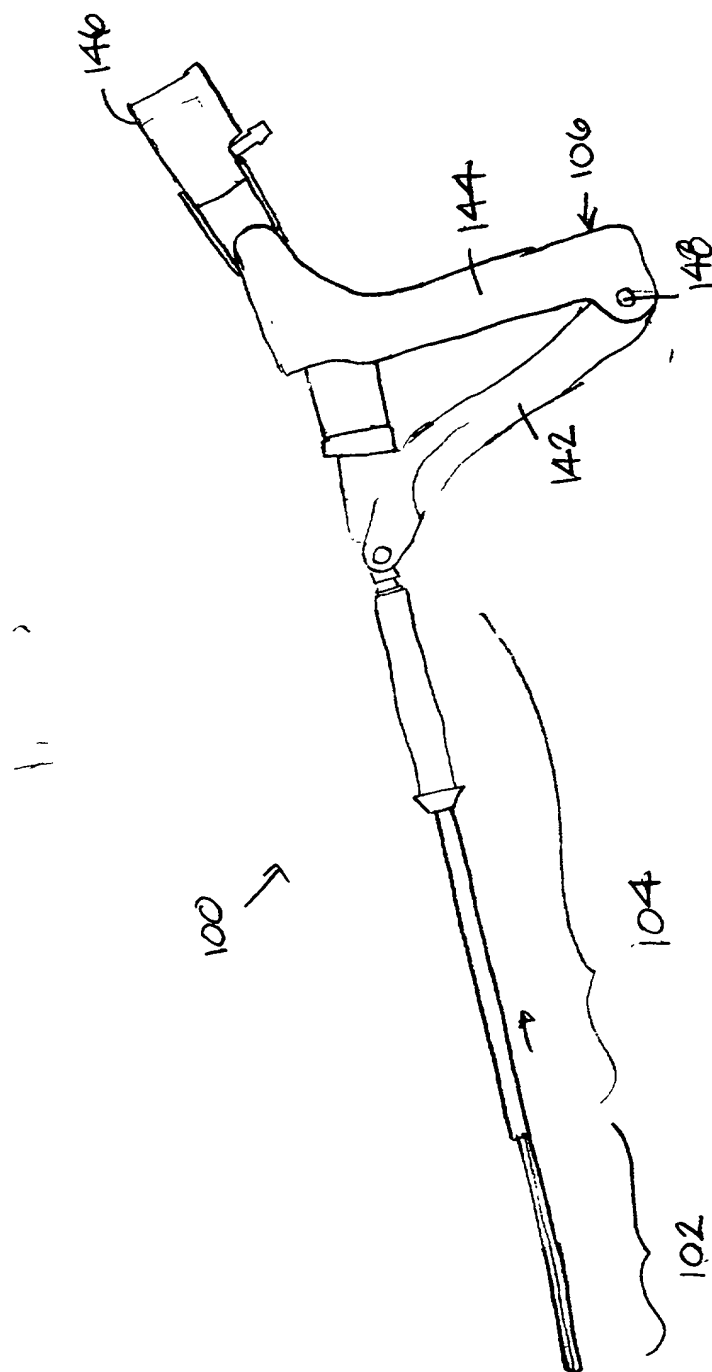


Fig. 22

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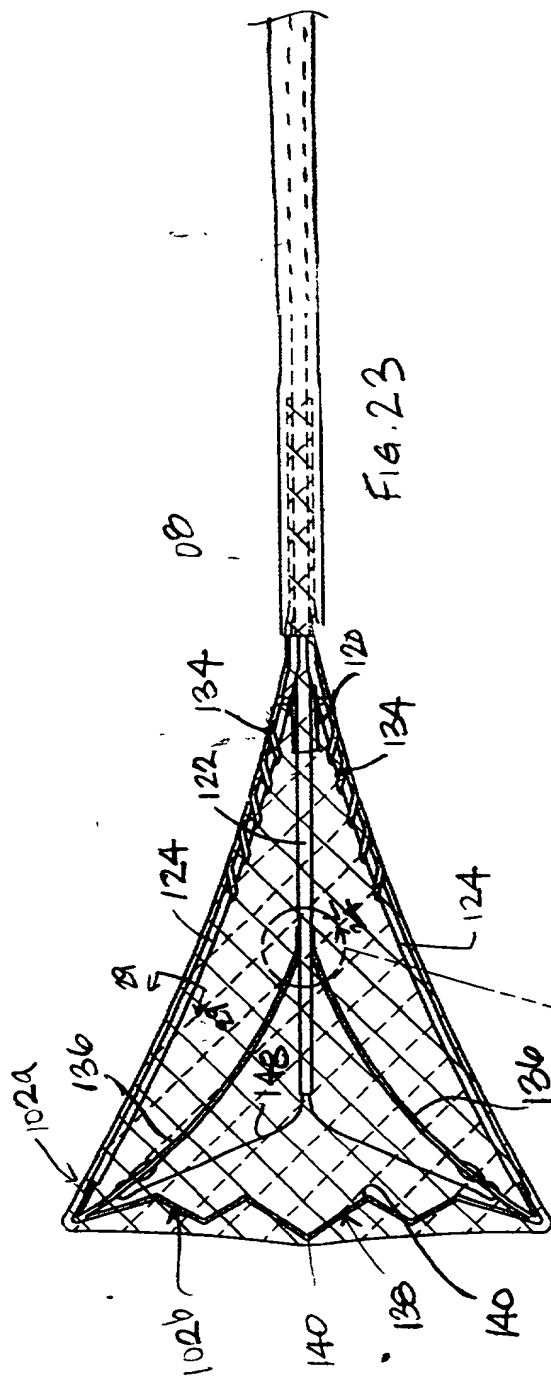


FIG. 23

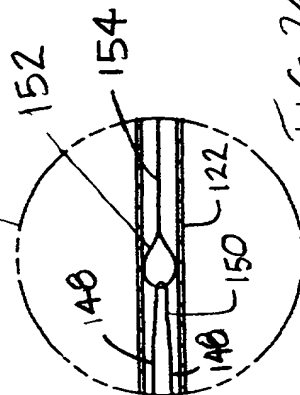
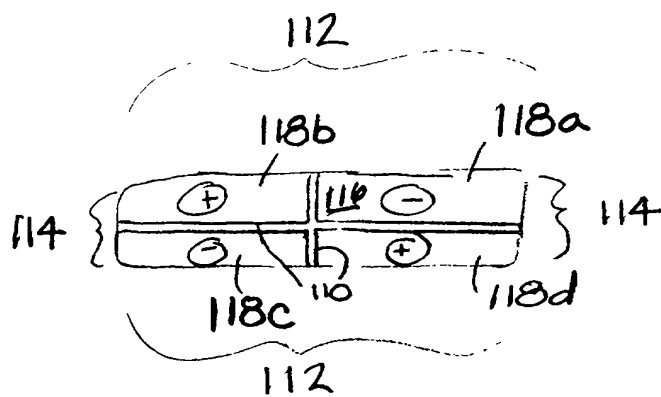
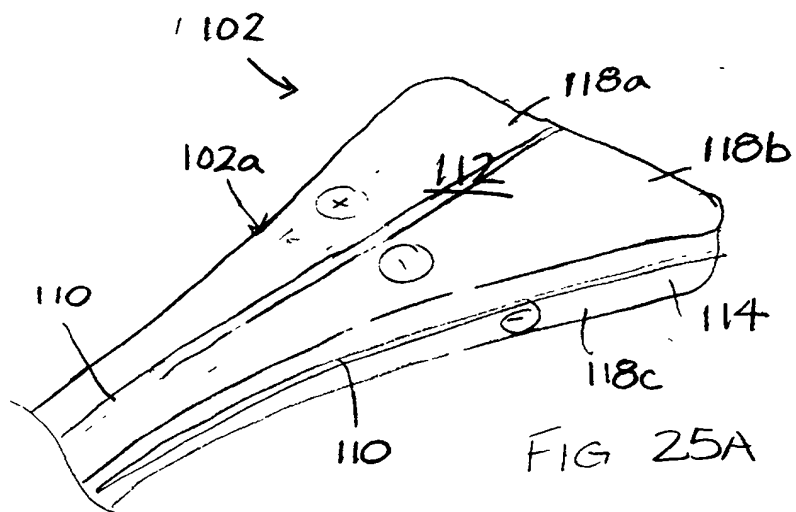


FIG. 24



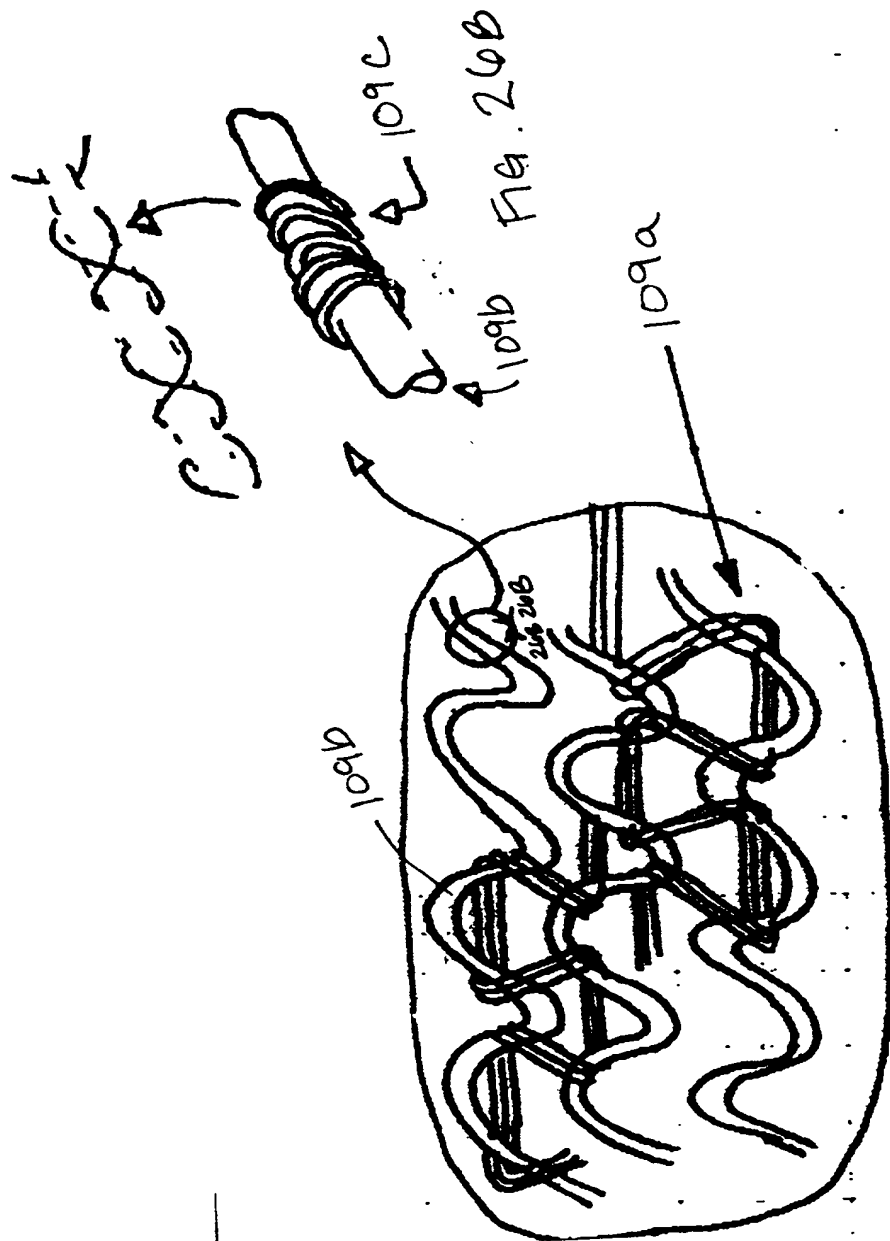


Fig. 26A

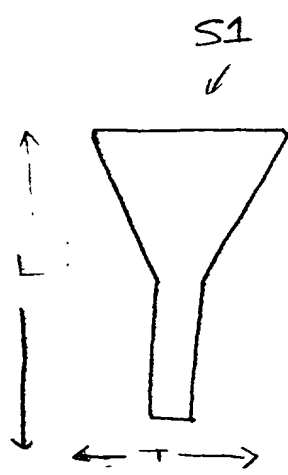


FIG. 27A



FIG. 27B



FIG. 27C

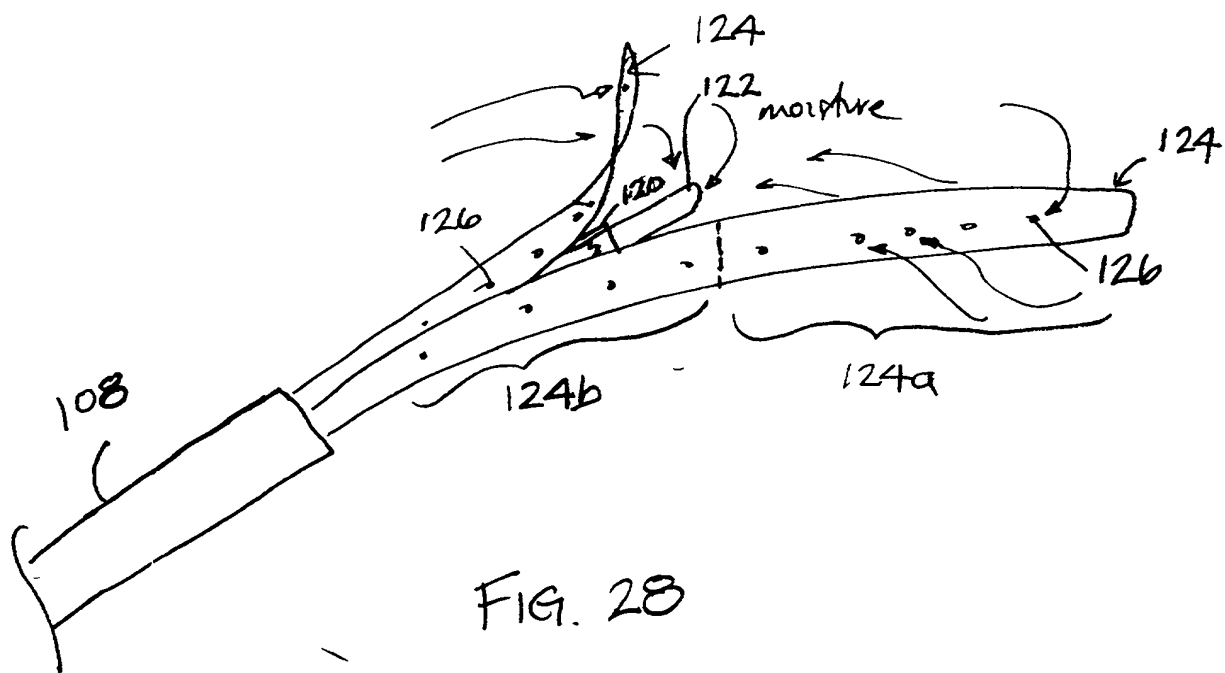


FIG. 28

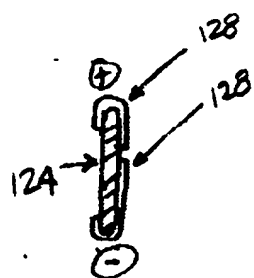


FIG. 29

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FIG. 30

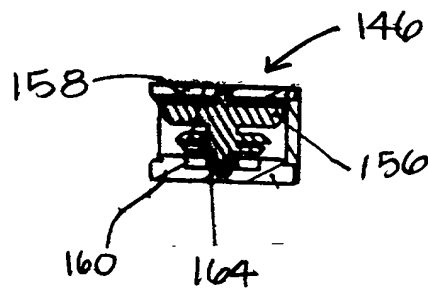
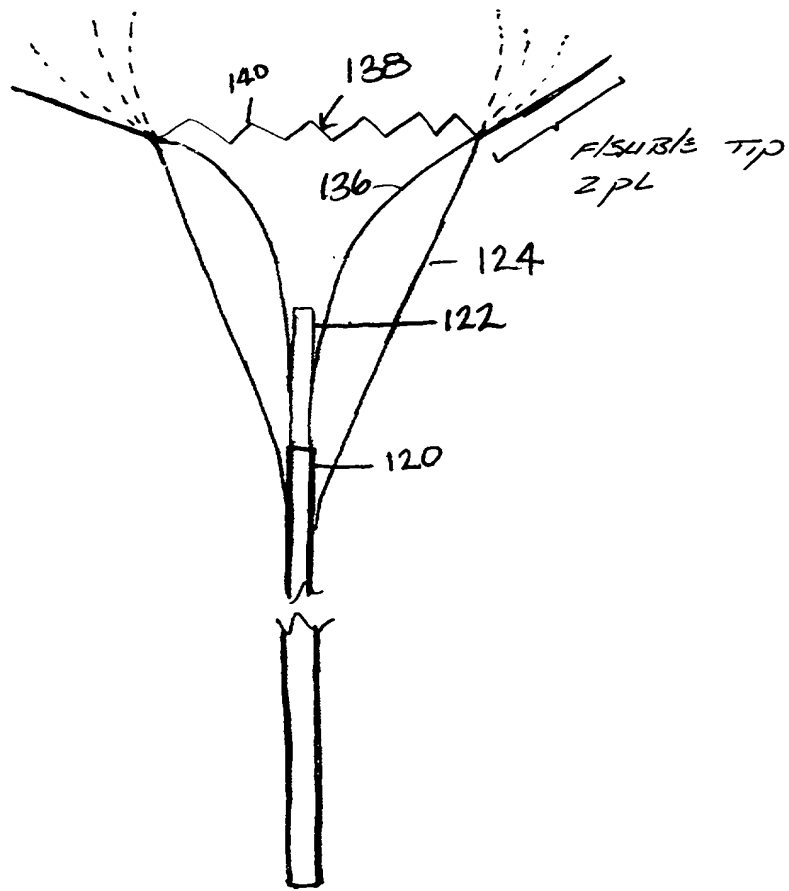


FIG. 31

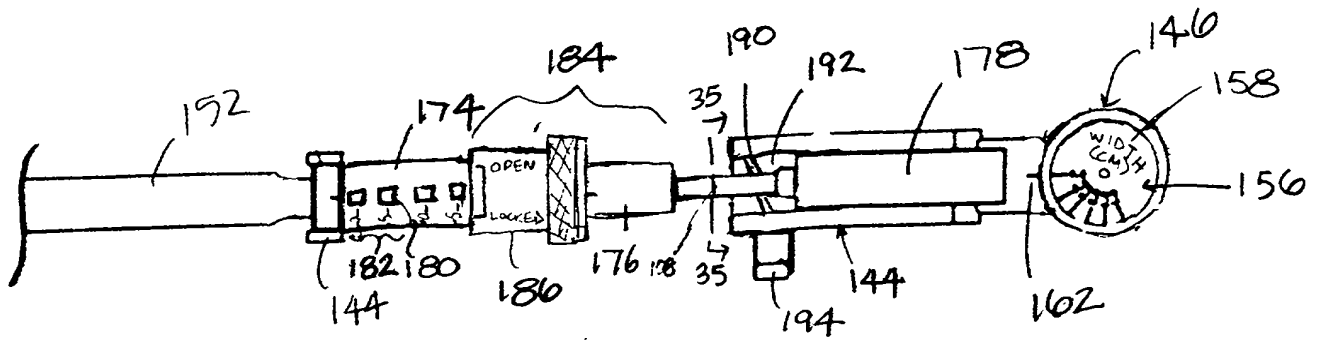


FIG. 32B

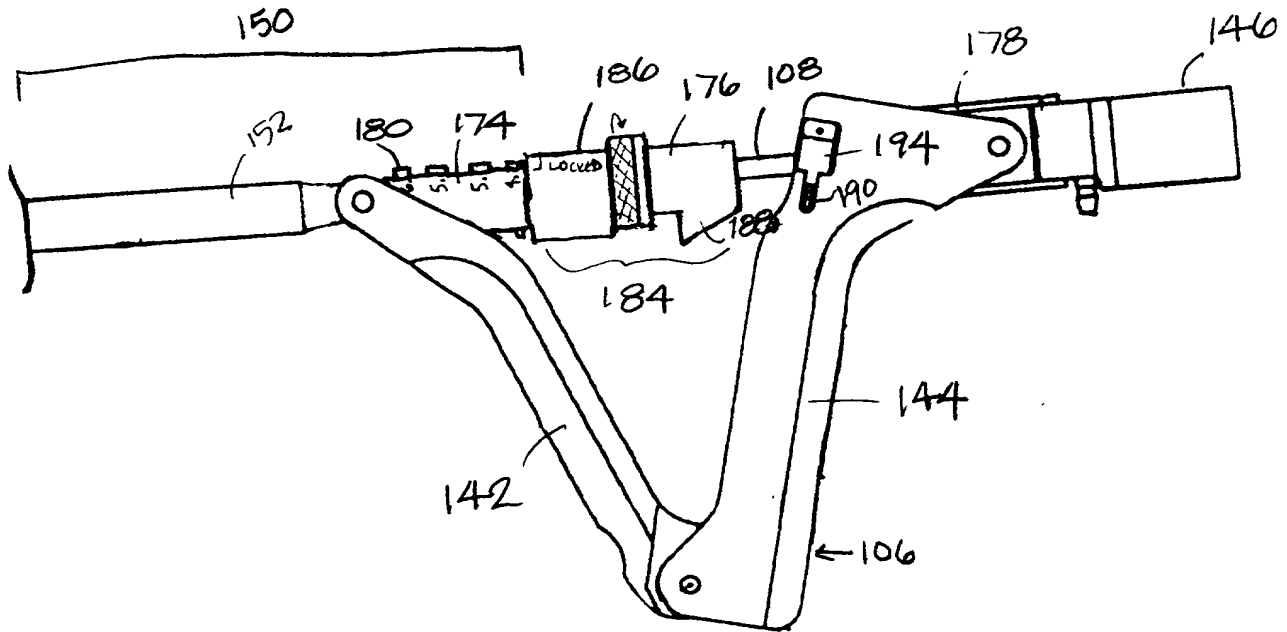


FIG. 32A

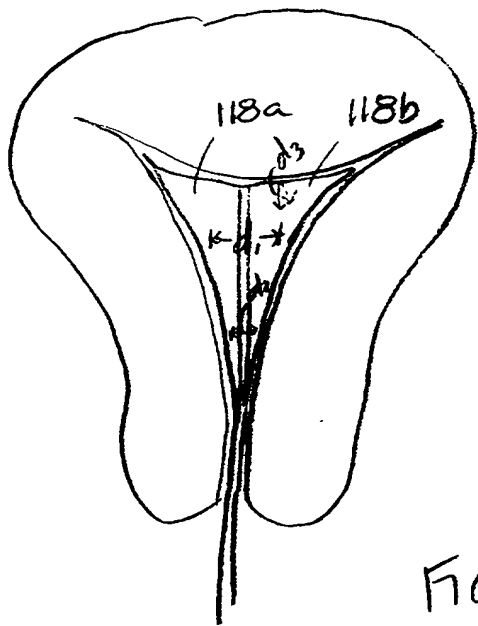


FIG 33

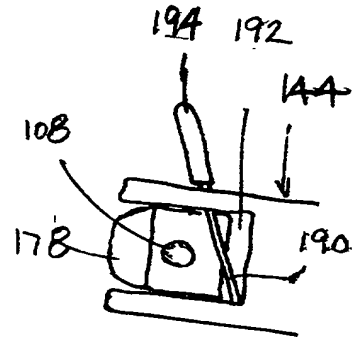


FIG. 35

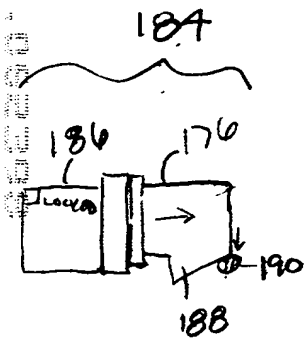


FIG 36A

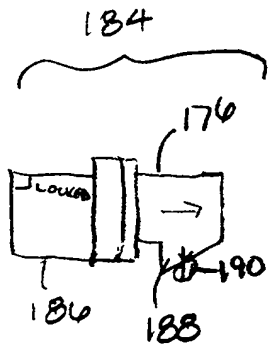


FIG 36B

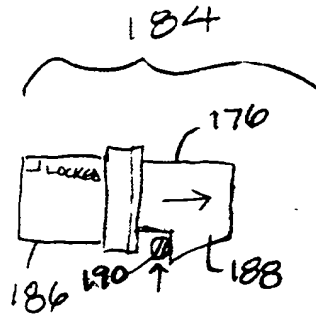


FIG 36C

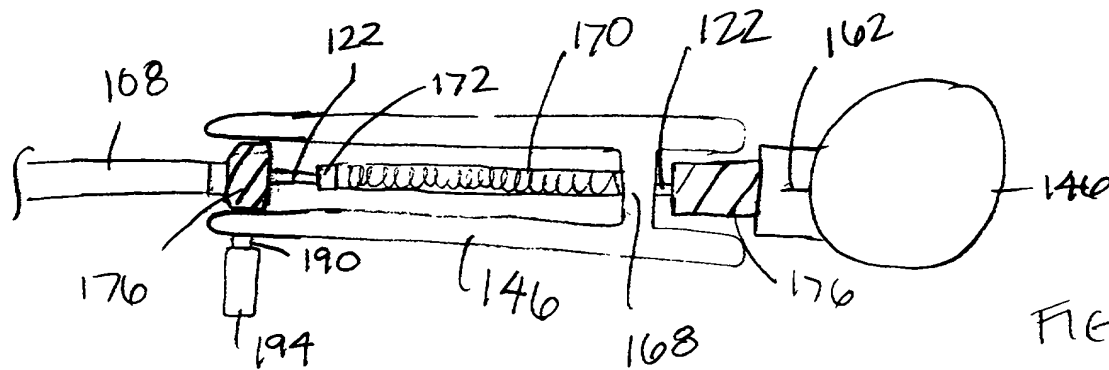


FIG. 37A

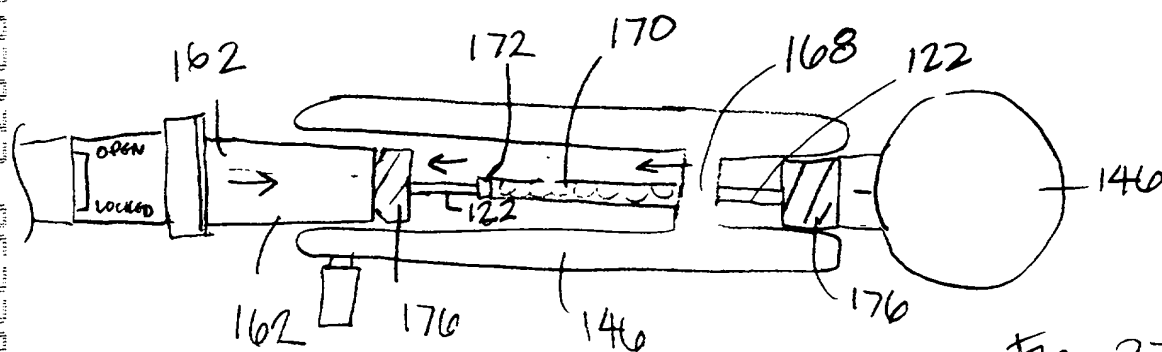


FIG. 37B

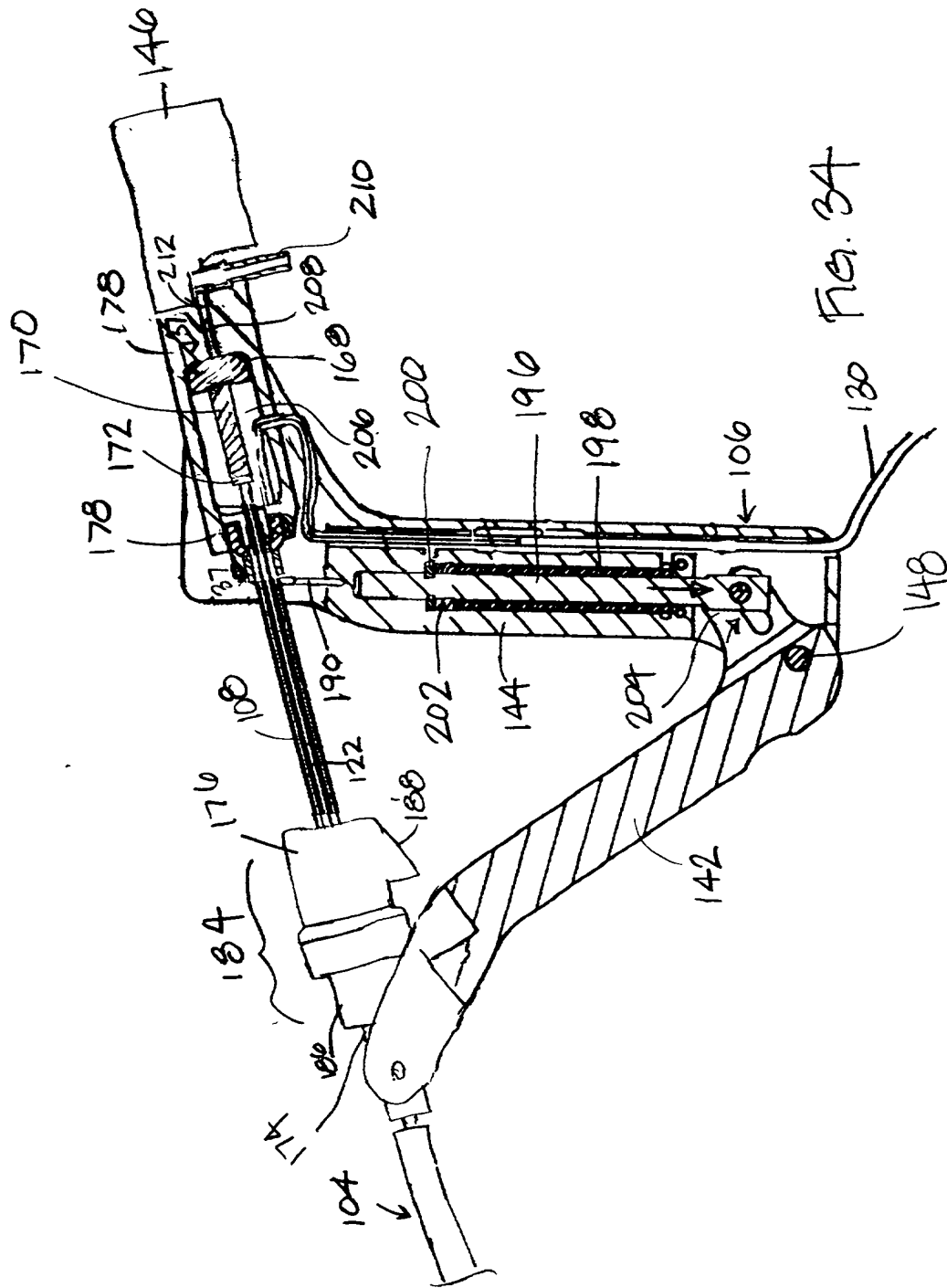


Fig. 34

DECLARATION FOR CIP PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION

the specification of which (check one) X is attached hereto or ___ was filed on ___ as Application No. ___ and was amended on ___ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
			Yes	No
Number	Country	Day/Month/Year Filed	_____	_____
Number	Country	Day/Month/Year Filed	_____	_____

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) below.

60/084,791	May 8, 1998
Application Number	Filing Date

Application Number	Filing Date
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I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

08/632,516 [Patent No. 5,769,880]	April 12, 1996	Patented
Application Number	Filing Date	Status: Patented, Pending, Abandoned

Application Number	Filing Date	Status: Patented, Pending, Abandoned
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Csaba Truckai

Inventor's signature _____ Date _____

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Citizenship USA

Post Office Address 627 Alberta Avenue, Sunnyvale, CA 94087

Full name of second joint inventor, if any, Russel Mahlon Sampson

Inventor's signature _____ Date _____

Residence 271 Diablo Ave, Mountain View, CA 94043

Citizenship USA

Post Office Address 271 Diablo Ave, Mountain View, CA 94043

Full name of third joint inventor, if any, Stephanie Squarcia

Inventor's signature _____ Date _____

Residence 411 California Ave, Apt. 14, Palo Alto, CA 94306

Citizenship USA

Post Office Address 411 California Ave, Apt. 14, Palo Alto, CA 94306

Full name of fourth joint inventor, if any, Alfonzo Lawrence Ramirez

Inventor's signature _____ Date _____

Residence 2911 Betsy Way, San Jose, CA 95133

Citizenship USA

Post Office Address 2911 Betsy Way, San Jose, CA 95133

Full name of fifth joint inventor, if any, Estela Hilario

Inventor's signature _____ Date _____

Residence 887 Altos Oaks Dr., Los Altos, CA 94024

Citizenship USA

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

☐ the owner of the small business concern identified below:☒ an official of the small business concern empowered to act on behalf of the concern identified below:NAME OF CONCERN NovaceptADDRESS OF CONCERN 1047 Elwell Court, Palo Alto, CA 94303

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled A MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION by inventor(s) Csaba Truckai et al. described in

☒ the specification filed herewith with title as listed above.☐ application no. , filed .☐ patent no. , issued .

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

NAME _____

ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

NAME _____

ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time or paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Csaba TruckaiTITLE OF PERSON OTHER THAN OWNER Vice Pres. of Research and DevelopmentADDRESS OF PERSON SIGNING 1047 Elwell Court, Palo Alto, CA 94303

SIGNATURE: _____

DATE: _____